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Bundesministerium für  
wirtschaftliche Zusammenarbeit  
und Entwicklung



# Local production of pharmaceuticals and health system strengthening in Africa

An Evidence Brief

A publication in the German Health Practice Collection

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## Acronyms and abbreviations

ACT	Artemisinin combination therapy
AMRH	African Medicines Regulatory Harmonisation
API	Active pharmaceutical ingredient
ARV	Antiretrovirals
AUC	African Union Commission
AVMI	African Vaccine Manufacturing Initiative
BMZ	Federal Ministry for Economic Cooperation and Development
DNDi	Drugs for Neglected Diseases
EAC	East African Community
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH
GMP	Good Manufacturing Practice
MDGs	Millennium Development Goals
MSD	Medical Stores Department, Tanzania
NCD	Non-communicable disease
NEPAD	New Partnership for Africa's Development
NGO	Non-governmental organisation
OOP	Out-of-pocket
PDP	Product Development Partnership
PTB	Physikalisch-Technische Bundesanstalt
PEPFAR	The US President's Emergency Plan for AIDS Relief
SDGs	Sustainable Development Goals
SSA	Sub-Saharan Africa
TB	Tuberculosis
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UHC	Universal Health Coverage
UNICEF	United Nations International Children's Emergency Fund
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization

# Executive Summary



## KEY INSIGHTS

### **Industrial development in pharmaceuticals in Africa can support health system strengthening**

Developing local pharmaceutical production can improve access to medicines and help to generate the scientific, technological and skills base for building stronger and more resilient health systems. These health-industry mutual benefits also depend on funding and managing competent, inclusive, population-focused health services, and on effective industrial regulation for quality assurance.

### **Local and global perspectives on emergency preparedness differ: both must be addressed**

Global health security frameworks focus on technologies for emergencies that threaten the wider world. African experts shift the focus onto breaking supply constraints for recurrent lethal emergencies by building local supply capacities and organisational expertise. Both contributions are needed to build medium-term health security.

### **External actors can support an upward spiral of health-industry synergies**

An upward spiral of industrial development and health system strengthening is emerging in some countries. External actors can support these synergies by linking up initiatives to strengthen access to medicines, through funding and procurement, to initiatives to strengthen the local industrial supplier base.



## CONTEXT

Low-income populations in sub-Saharan Africa (SSA) continue to suffer inadequate health care, undermined by poor access to medicines. In the context of Sustainable Development Goal (SDG) 3 and international commitments to universal health coverage (UHC), international intervention finances large-scale international procurement of medicines and supports health system strengthening. Meanwhile, pharmaceutical manufacturing in SSA is long established, and is currently being promoted by African governments and other actors including the African Union Commission (AUC), the New Partnership for Africa's Development (NEPAD) and the East African Community (EAC), and supported also by external actors including Germany's Federal Ministry for Economic Cooperation and Development (BMZ). This Brief presents evidence for the actual and potential health and development benefits from creating stronger local and global linkages between these industrial and health agendas, and outlines how this can be done.

## THE SCOPE FOR LOCAL UPWARD SPIRALS: 'WIN-WINS' FOR HEALTH AND INDUSTRIAL DEVELOPMENT

Industrial development in pharmaceuticals is currently observed to be interacting in a number of African countries with rising commitment to local funding of health supplies and to health system strengthening, in a virtuous upward spiral. Once underway, a mutual benefit lobby can emerge between local health system actors anxious to reduce supply shortages and arguing for higher public funding, and local industrialists looking for larger markets. A 'local health' policy perspective identifies local health priorities and existing industrial capabilities, and then builds synergies and on-the-ground linkages between industrial and health system investments. In this way, local industrial development in pharmaceuticals can support health system strengthening through:

- increased national government commitment to funding of medicines from domestic taxes, improving medicines access;
- improved pharmaceutical skills and training benefiting health system management and procurement as well as industrial development;
- public and non-profit procurement becoming more responsive to local needs, by building linkages to close-to-market suppliers;

- improved rural access to medicines, as local firms respond to incentives to expand domestic distribution networks;
- falling costs and prices as domestic industrial investment and market competition increase;
- shortened supply chains and hence faster response to emergency supply shortages; and
- reduced incidence of sub-standard medicines, as proximity improves regulatory oversight and the share of public and non-profit procurement rises.

Many of these benefits are medium term: they require patience and commitment to build local health-industry linkages within markets and policy. This medium-term vision is also driving African commitments to building local scientific and technological capabilities for production of vaccines and more complex treatments.

## HOW EXTERNAL ACTORS CAN SUPPORT THE MUTUAL HEALTH-INDUSTRY BENEFITS

External actors such as BMZ, who both work on health system strengthening and also support industrial development, are well placed to link up these policy 'silos'. Key areas where policies can have major mutual health-industry benefits include: regulatory strengthening and harmonisation; technological upgrading and improved quality assurance in local manufacturers; investment in skills and training in clinical and industrial aspects of pharmaceuticals at all levels; and strengthening local procurement by international and local agencies through improved local health-industrial collaboration and market linkages. In working for mutual health and industrial improvement, an open-minded, project-based and problem-solving approach can extract early mutual benefits and generate moves towards policy coherence over time.

## INDUSTRIAL DEVELOPMENT IS A SOCIAL DETERMINANT OF HEALTH

Public health has enlarged its vision recently to include many intersectoral social determinants of population health. However, the impact of industrial development on health is still generally overlooked. Building more robust African health systems requires – and will effectively employ – the scientific and technological capabilities and skills generated by industrial development in pharmaceuticals. As African governments develop their commitment to industrialisation, the global health community has much to contribute in supporting local health systems to extract the maximum benefits for public health.

# Opening reflection: two perspectives on health security

The authors of this Brief on local pharmaceutical production in Africa and its links to health system strengthening were asked to include evidence on the contribution of local production to pandemic and emergency preparedness. That request reflects the rapidly rising concern for health security and epidemic preparedness evident in the global health literature and within funding priorities. Contributions in the global literature, predominantly from industrialised country authors in disciplines including security studies, development, foreign policy and international relations, tend to focus on protection of their citizens against ‘external [health] threats’ (Aldis 2008). At inter-governmental level, the first-ever United Nations Security Council resolution on health was 1308<sup>1</sup>, adopted in July 2000, addressing the HIV/AIDS pandemic and its impact on peace and security (Rokvic and Jeftic 2015). There followed other resolutions that covered the SARS outbreak in 2003, the H1N1 pandemic in 2009, and the Ebola outbreak in 2014 (Rokvic and Jeftic 2015). In academic and policy discussions ‘health security’ has particularly addressed cross-border fast-moving infectious diseases, HIV and biological weapons/bioterrorism (Rushton 2011). A *WHO Bulletin* Editorial (Flahault et al 2016) recognises that ‘the concept of global health security underpins the current framework for global preparedness and response to emerging infectious diseases’, aiming to strengthen global capabilities to detect, respond to and prevent their spread. Attention has focused on protecting the public health of high-income countries against infectious diseases emanating from low- and middle-income countries.

However, when we asked East African expert interviewees -- clinicians and pharmacists from the health sectors of Kenya and Tanzania -- about their priorities for emergency preparedness, their responses were sharply different from this global health perspective. With no exceptions, they prioritised current emergencies from which many people

are dying now. In Tanzania, two pharmacists and a district medical officer identified as priorities dealing with recurrent shortages of emergency medicines such as saline drips, oral rehydration salts, oxytocin, hydrocortisone, magnesium sulphate and adrenaline. These shortages repeatedly cause deaths of children and adults in emergency situations. Both Tanzanian and Kenyan Ministry of Health respondents also prioritised sustaining the supply of antiretrovirals (ARVs) for HIV and artemisinin combination medication (ACTs) for malaria as priorities to avoid potential large-scale emergencies. Furthermore, the African respondents, when asked specifically about pandemic preparedness, prioritised building local scientific capabilities to address pandemics, including local vaccine manufacturing capability, intellectual property-linked partnerships with multinationals, and use of flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). African respondents more broadly drew from experience an understanding that when nation states are faced with health emergencies, governments first protect their own nationals. The 2008-2009 flu pandemic was cited as a case where there was no plan to manufacture vaccines simultaneously for national and international requirements <sup>2</sup>.

These different perspectives on emergency preparedness, which are not necessarily in contradiction, are explored further below. However, contrasts between arguments and frameworks of analysis of the health implications of the geographical location of productive and scientific capabilities, between the ‘international’ literature on the one hand and debates and policies within sub-Saharan Africa (SSA) on the other, run through this Brief as a whole.

<sup>1</sup> The resolution can be consulted at [www.undocs.org/S/RES/1308\(2000\)](http://www.undocs.org/S/RES/1308(2000))

<sup>2</sup> Ethiopian expert commentator, 2011.

# Context and questions

## INDUSTRIAL AND HEALTH CONTEXTS

In international research and policy debates, health system strengthening and industrial development have been and largely continue to be addressed within two separate silos (Mackintosh et al 2007, 2016a). In African government policy, and within pan-African institutions of research and policy, however, this has been changing. There is now strong recognition within African contexts that there are potentially large developmental synergies to be extracted between expansion of industrial production of pharmaceuticals and medical supplies and improvement of the coverage and quality of health care, especially for their low-income populations (African Union, 2007, 2012; EAC 2011; Berger et al 2010; Government of Kenya 2010; URT 2016; Government of Uganda 2002; FDRE 2015; Gebre-Mariam et al 2016; Republic of Ghana 2004). International thinking has also shifted: the current World Health Organization (WHO) strategic framework for medicines and health products (WHO 2017a: 8,12) recognises the relevance of local manufacturing of quality medicines and health products to support access, a view earlier emphasised by a joint declaration by the heads of the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Industrial Development Organization (UNIDO) and WHO (Sidibé et al 2014), rooted in joint work by WHO, the United Nations Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD) (WHO 2011a, UNCTAD 2011). By 'local' manufacturing, throughout this Brief, we mean manufacturing geographically located in low- and middle-income countries, and specifically in SSA, independent of ownership.

Potential and actual synergies between local production of medicines and health commodities and access to medicines and treatment arise from market linkages. Health care constitutes a huge global market for industrial commodities: the global market for pharmaceuticals was estimated at USD 1072 billion in 2015 (Statistica 2017). Africa's estimated

USD 20.8 billion (2013) share is small but rapidly growing (McKinsey & Co 2015). Medical supplies, devices and equipment also constitute very large markets for industrial goods. African market size has been boosted by a huge inflow of philanthropic and governmental development aid for health since 2009. Of the estimated USD 36 billion development assistance for health in 2014 (the last year for which a breakdown of recipients is available), the share going to Africa was estimated at USD 14 billion, of which around USD 5.7 billion was earmarked for HIV (IHME 2017). The proportion of these funds going to purchase medicines and supplies is substantial but hard to establish. The Global Fund to Fight AIDS, Tuberculosis and Malaria (henceforth The Global Fund) estimates a spend of nearly USD 2 billion in 2016 on health products, mainly medicines and diagnostics, through all its procurement channels, with a substantial share for African countries<sup>3</sup>. This is more than half of their USD 3.55 billion grant disbursements for 2016 (The Global Fund 2017). Health policies thus inevitably shape markets for industrial producers, for benefit or detriment (Reich 1990; Thomas 1994; Srinivas 2012).

From the health side, and despite this inflow of funds, low-income populations in SSA continue to suffer severely inadequate and exclusionary health care undermined by poor access to medicines and supplies (Wirtz et al 2017; Bigdeli et al 2014; Wagner et al 2011; WHO 2011b). Median availability of essential medicines 2007–2014 was only 60% overall, and 56% in the public sector of low-income and lower-middle-income countries (WHO 2017b: 11). This availability has changed little over the period in African countries with time-series data (UN 2015: 55–6). While global health disparities have been reduced in absolute terms by concerted efforts to achieve the Millennium Development Goals (MDGs) and other health-related initiatives (WHO 2013), major challenges remain in terms of reducing maternal and child mortality, improving nutrition, and making further progress in the battle against communicable diseases including HIV, tuberculosis (TB), malaria, neglected tropical diseases and hepatitis (WHO 2017b).

<sup>3</sup> Data provided by The Global Fund.



The WHO African Region had the highest under-five mortality rate (81.3 per 1000 live births) in 2015, almost double the global rate. The region also remains the worst affected by HIV, with SSA alone contributing 75% of the 1.8 million new infections globally in 2015 (GBD 2015 HIV Collaborators, 2016). While there has been a 41% decline in recorded malaria cases between 2000 and 2015, Africa bears more than 90% of the remaining global burden of the disease: in 2015, of the 429,000 malaria deaths recorded, 92% were in Africa, with children under five years accounting for more than 70% (WHO 2017b, 2016). Non-communicable diseases (NCDs) are also rising, as shown by the high prevalence of hypertension, a key tracer indicator of health services for cardiovascular diseases which has not declined in many low-income countries in Africa and Asia since 2000. The burden of NCDs in the WHO African Region is predicted to overtake the burden of mortality and morbidity from communicable diseases by the year 2030, due in part to lack of commitment to fund and implement measures to address the key risk factors for NCDs (WHO 2015).

International commitments to work towards universal health coverage (UHC) globally recognise the extent of the challenge in Africa (World Bank 2016), while the adoption of the Sustainable Development Goals (SDGs) has focused attention on improving inclusiveness of health systems. Unlike MDGs (2000-2015) which focused on programmes tailored to specific health conditions, SDG3 gives attention to performance of whole health systems including access to safe and affordable medicines and vaccines, and the prevention of epidemics (WHO 2017a, 2017b). Better access to essential medicines and more appropriate use are required for all the aspects of health system strengthening listed in the UHC 2030 Joint Vision (WHO/World Bank 2017): for reducing severe inequity, and improving quality, responsiveness, efficiency and resilience.

The context for this evidence brief is thus the convergence of continuing need in Africa for better access to essential medicines and supplies with expanding Africa-based industries producing pharmaceutical and health sector supplies. Pharmaceutical manufacturing in SSA is – contrary to some external perceptions – long established and quite extensive (Banda et al 2016a), with long-standing industrial strengths in South Africa, Kenya and Nigeria in particular.

## QUESTIONS

This Evidence Brief addresses the linkages – positive and negative – between local industrial production of pharmaceuticals in Africa and strengthening of African health systems. German development cooperation is supporting industrial development, including investment and upgrading of local pharmaceutical industries and the regulatory systems supporting them <sup>4</sup>. It is also focusing on health system strengthening in Africa, using an approach that aims to address interactions between health system components and also the impact of other sectors, such as education, on the performance of health systems <sup>5</sup>. This Brief identifies ways in which industrial development can generate benefits for health, and *vice versa*.

We therefore do *not* ask one question familiar from the literature and debates – ‘Should Africa produce medicines?’ (Kardas-Nelson 2015) – since Africa has long done so and aims to produce more. We move away, furthermore, from another framing question in the international literature: ‘Does local production of medicines in Africa benefit health care?’ Kaplan et al (2011) is a systematic review based on this approach. For our purpose here, this question is too broad to be usefully answerable: Any answer for policy purposes is, necessarily, ‘It depends’. This Evidence Brief therefore asks the more policy-relevant question, ‘What do beneficial health-industry linkages *depend on*?’ It asks specifically:

- What are the factors that can and do sustain a positive health-industry spiral of mutual benefit?
- To what extent have these factors been achieved?
- Where and why have the linkages gone wrong?
- What could be done to strengthen them?

<sup>4</sup> GIZ: <http://eacgermany.org/wp-content/uploads/2017/02/GIZ-EAC-Factsheet-Socio-Economic-Integration-in-the-EAC-SCREEN.pdf>; PTB: <https://www.ptb.de/lac/index.php?id=eac>; UNIDO: <http://www.unido.org/pharmaceuticals.html>; UNCTAD: <http://unctad.org/en/Pages/DIAE/Intellectual%20Property/Building-local-pharmaceutical-production--supply-capacity.aspx>

<sup>5</sup> [www.health.bmz.de/what\\_we\\_do/hss/Healthy\\_Systems-Healthy\\_Lives/index.html](http://www.health.bmz.de/what_we_do/hss/Healthy_Systems-Healthy_Lives/index.html)

# Methods and perspective: local health in a globalised world

## METHODS

This Brief is written by four authors: three of us collaborated on a recent edited book, *Making Medicines in Africa* (Mackintosh et al 2016a), and have other recent research on pharmaceuticals and health systems in Africa<sup>6</sup>; the fourth is a researcher at a Tanzanian research and policy institution<sup>7</sup>. Here we assemble and reflect upon the following sources of evidence:

First, we updated and expanded the existing literature reviews for the *Medicines* book and other projects. As part of this process, we searched policy documents and ‘grey literature’ on a wide range of topics related to local production of pharmaceuticals in low- and middle-income countries, access to essential medicines and health sector supplies, and health system strengthening in SSA, and have assessed the quality of evidence. However this is not a systematic review: the criteria for inclusion in such reviews would retain too narrow a range of evidence for the questions addressed here.

Second, we have used and updated primary and secondary data and interviews from East Africa, with a particular focus on Kenya and Tanzania. The Brief draws on primary data collected by one of the authors and Kenyan and Tanzanian colleagues between 2012 and 2015<sup>8</sup>. This primary evidence has been supplemented by 23 interviews undertaken in East Africa (Tanzania, Kenya, Uganda) in April-May 2017. Many of these interviews involved multiple interviewees; they included six discussions with manufacturers, several of whom hold additional policy-related roles in manufacturing associations or philanthropic organisations; three with wholesalers (procurement agencies or private distributors); three in regulatory bodies; two government ministry interviews; three with

clinicians and pharmacists working in the health sector; two in university-level pharmaceutical education; two with consultants working in the pharmaceutical sector; and two with East African Community officials; we also met a group of senior informants at The Global Fund in Geneva. In addition, evidence is drawn from discussions by authors with a broader network of African experts, in the context of meetings and consultations on local production in Africa. All interviewees’ responses are unattributed, except where specific permission has been obtained.

## PERSPECTIVE: GLOBAL HEALTH AND LOCAL HEALTH

The global health field, with its focus on issues that ‘transcend national boundaries and governments’ (Kickbusch 2006), builds on earlier international health work that extended public health concerns across geographical boundaries (Battams and Matlin 2013; Macfarlane et al 2008) to address tropical infectious diseases, access to safe water, combating malnutrition and promoting maternal and child health: a ‘synthesis of population-based prevention with individual-level care’ (Koplan et al 2009). Global health initiatives aim to address vast international disparities in mortality, morbidity and human wellbeing. Campaigning and literature have focused around initiatives by ‘global’ – that is, high-income country-based – actors to address these disparities. The major funding initiatives, by The Global Fund, the US President’s Emergency Plan for AIDS Relief (PEPFAR) and other multilateral and bilateral agencies have had hugely beneficial health effects, both in directly saving lives, and also, importantly, in reframing understanding and obligation within high-income countries.

<sup>6</sup> See for example Mackintosh et al (2016b); Tibandebage et al (2014); Banda et al (2016b); Tait and Banda (2016); Mugwagwa (2015).

<sup>7</sup> The Economic and Social Research Foundation, Dar es Salaam, Tanzania <http://www.esrf.or.tz/>

<sup>8</sup> The methods and initial outputs of that project are available on the project website [www.iphsp.acts-net.org](http://www.iphsp.acts-net.org). The project, *Industrial Productivity and Health Sector Performance*, was funded by DFID and the UK Economic and Social Research Council (ESRC): the usual disclaimer applies (see Acknowledgements).

A concern with industry-health linkages does, however, identify key limitations of the 'global health' framing of analysis and policy. The focus on top-down, cross-border initiatives has diverted attention from developmental health-industry linkages within national, e.g. African, economies. Furthermore, the dominant public health perspective, while addressing some of the social determinants of health beyond the health system (Battam and Matlin 2013; CSDH 2008), largely ignores the role played by industry and by medical technological development in determining the operation of health systems. It also discounts the ways in which industrialisation and growth can underpin improving population health (López-Casasnovas et al 2005). The underlying global health assumption has been that medical health technologies are commodities readily available from global pharmaceutical value chains, and that affordability, timely availability and access are best addressed by global procurement, largely from Indian manufacturers. This perspective was reinforced by the dramatic successes in lowering prices for, especially, HIV medicines (MSF 2016; Waning et al 2010).

This Brief summarises evidence relevant to high-income countries' aid policies and, in that sense, is a contribution to the global health field. However, it examines its evidence, on local manufacturing in Africa and its linkages to health systems, within a 'local health' perspective. That is, we are concerned centrally with local health-industrial synergies and their impact on developmental and health-related resilience within SSA. While recognising that African health systems and manufacturers of medicines and other health products operate in strongly globalised markets, we summarise evidence on how these market, competitive and policy pressures are shifting, and the scope for the strengthening of local capability and agency. We focus on the scope for building competitive, high-quality local suppliers; the potential and actual benefits for local health systems; and the impediments, failures and hurdles to be overcome.

# Beneficial health-industry linkages: scope for an upward spiral

## OUR CONTENTION: LOCAL PRODUCTION OF MEDICINES CAN STRENGTHEN HEALTH SYSTEMS

Local health systems are culturally embedded social and economic institutions that must be built within national jurisdictions, and in Africa within the highly challenging context of liberalised trading conditions, cross-border investments, conditionalities on development aid for health, and highly constrained domestic health finance. There is no simple correlation – positive or negative – between national industrial development in pharmaceuticals in Africa and access to medicines and appropriate treatment. Nigeria, for example, has a large pharmaceutical industry, but a very underfunded public health system and its population faces major financial constraints on access to treatment and a historically severe problem of counterfeit and substandard medicines (Wirtz et al 2017; Onwujekwe et al 2011; WHO 2011c). The Democratic Republic of Congo (DRC) lacks a large pharmaceutical industry and offers its population still worse access to reliable medicines, even in Kinshasa (ACT Watch Group et al 2017a). Outside Africa, India fails, despite its powerful pharmaceutical industry, to provide its people with reliable and equitable access to medicines (Srinivas 2016; Mackintosh et al 2016b). Conversely, Bangladesh, which has rapidly expanded its local pharmaceutical industry, has also achieved striking health care improvements (Ahmed et al 2013; Chowdhury et al 2013). Whatever its industrial status, no country that lacks a government commitment to ensuring socialised funding and competent management of inclusive, population-focused health services can meet its population's requirements for universal access to essential, good-quality medicines.

Our contention in this Evidence Brief is thus *not* that industrial production of pharmaceuticals is necessarily associated with good access to medicines. Rather, we argue that African and international evidence shows that local production of medicines *can* strengthen health systems.

The determinants are national context and policy processes, and external actors may support – or derail – both. The rest of this section draws mainly on evidence from East Africa, with some less detailed evidence from other regions of Africa.

## LOCAL PHARMACEUTICAL PRODUCTION AND THE DOMESTIC MEDICINES MARKET IN EAST AFRICA: CONTEXTUAL BENCHMARKS

The context for analysing the health impact of local pharmaceutical production in East Africa is, first, the scale and expansion of the industry to date, and second, its market structure and competition. The largest East African pharmaceutical industry is in Kenya, made up of 39 firms (as of 2014) located mainly in and around Nairobi (Simonetti et al 2016; UNIDO 2010a)<sup>9</sup>. Most firms produce basic essential formulations, tablets and capsules, syrups for children, and some creams. Two firms produce parenteral preparations, and one has been piloting production of the active anti-malarial ingredient artemisinin. One firm, Universal, has WHO-prequalification of a product line, allowing it to bid in international tenders funded, for example, by The Global Fund. Most firms in Kenya are East African-owned. However Universal has just been taken over (51%) by Strides, a leading Indian pharmaceutical manufacturer, and Beta Pharmaceuticals is now owned (100%) by Aspen, a South African-based multinational. A variety of estimates, including unpublished primary survey data, and estimates from trade and production survey data (see Table 1) show that around one-third of Kenyan essential medicines consumption is of locally produced medicines. Kenya is also the only fairly substantial regional exporter of pharmaceutical products (see Figure 1 p. 15).

<sup>9</sup> Details that follow are also drawn from interviewing in Kenya 2014–15, and 2017.



**TABLE 1. KENYA AND TANZANIA: PHARMACEUTICAL MARKETS 2009 AND 2013 (MILLION CURRENT US DOLLARS) AND MARKET SHARE OF LOCAL MANUFACTURERS (%)**

COUNTRY AND YEAR	(1) IMPORTS (USD M)	(2) EXPORTS (USD M)	(3) LOCAL PRODUCTION (USD M)	LOCAL MARKET SHARE (%) <sup>*</sup>
<b>KENYA</b>				
2009	298.6	67.3	99.9	30
2013	466.4	82.1	193.1	33
<b>TANZANIA</b>				
2009	99.4	7.9	49.2	35
2013	286.1	1.7	48.7	15

\*Share calculated as (3) / ((1) + (3) - (2))

Sources: Author calculations from the following sources.

Kenya: Imports, exports and local production: KNBS 2014, 2015. Mid-year exchange rates from Central Bank of Kenya ([www.centralbank.go.ke/](http://www.centralbank.go.ke/)), consulted 17.2.16).

Tanzania: Imports and exports: Comtrade data base ([www.comtrade.un.org/data/](http://www.comtrade.un.org/data/)), downloaded 5.8.14; local production URT (2012, 2013). Mid-year exchange rates from Bank of Tanzania ([www.bot-tz.org/](http://www.bot-tz.org/)), consulted 12.2.16).

Other East African countries have smaller pharmaceutical industries. Uganda in 2009 had 11 operating pharmaceutical firms (UNIDO 2010b), later expanded to 13 (EAC 2011). They include CIPLA Quality Chemicals, a joint venture which is now wholly integrated into the Indian multinational CIPLA and which has WHO prequalification for some products; and also Kampala Pharmaceutical Industries, part of the Aga Khan network and the largest pharmaceutical manufacturer in Uganda. The number of operating pharmaceutical firms in Tanzania fell from eight in 2009 to five in 2014, with a resultant collapse in local firms' market share (Tibandebage et al 2016) (see Table 1); it now (early 2017) stands at six, including a newly opened firm. Three firms in Tanzania are locally owned, of which two are small; one larger firm has recently been sold to Kenyan private equity capital, and the largest firm, Shelys, has been acquired by Aspen. Two other EAC members, Rwanda and Burundi, each have one pharmaceutical company.

In the wider Eastern and Southern African region, Ethiopia is emerging as an expanding producer, with nine pharmaceutical firms including Sino-Ethiop Associate (Africa), a joint venture producing and exporting hard gelatin

capsules (Gebre-Mariam et al 2016). In Southern Africa, Brazilian capital was invested in a firm in Mozambique (Russo and de Oliveira 2016); Zimbabwe has sustained some pharmaceutical production through its economic crises (Banda et al 2016a); and the largest producer by far is South Africa, which also has some capability to produce active pharmaceutical ingredients (APIs) (Berger et al 2010).

Local industry–health linkages in East Africa and their access implications are structured by the extent of the populations' reliance on private purchase of medicines. Stock-outs in public sector facilities and resultant reliance on out-of-pocket (OOP) purchase of medicines continue to exclude low-income populations across SSA from reliable access to treatment (Bigdeli et al 2014; WHO 2011b; Ewen et al 2017). The problem is well documented in East Africa, even for the medicines supplied by international initiatives (Church et al 2017; Sudoi et al 2012; Talisuna et al 2012). Recent research confirmed widespread and recurrent public sector stock-outs in both Kenya and Tanzania (Kariuki et al 2015; Tibandebage et al 2014), with interviewees then, and for this Brief, confirming that patients are regularly sent to buy medicines from



shops. An official Kenyan estimate (MoMS & MPHS 2010) put the private share of total pharmaceutical expenditure at 80%; interviewees in Tanzania estimated that roughly half of medicines purchases were in the private sector. OOP expenditure on health was estimated at 26% (Kenya) and 23% (Tanzania) of total health expenditure and much of that spending will have been on medicines<sup>10</sup>.

## POTENTIAL ‘WIN-WINS’ FOR INDUSTRIAL DEVELOPMENT AND HEALTH SYSTEM STRENGTHENING

In this challenging context, the following are the areas of ‘win-win’ initiatives that *can* benefit *both* industrial development and health system performance. We provide evidence of the potentialities and of the impediments that can produce the opposite effect.

### Industrial development objectives can generate larger fiscal commitments for medicines access

A combination of fiscal constraint, competing political priorities and reliance on donor funding for medicines procurement has sharply squeezed domestic tax-based funding for medicines in Tanzania and Kenya in recent years (Mackintosh and Tibandebage 2016). This squeeze has exacerbated public sector stock-outs of essential medicines that are not supplied by donor-funded programmes, including antibiotics and medicines for NCDs, pushing patients into the private market. Public sector prices are generally (though not always) lower than private sector prices for patients, and prices are zero for some patients in the public sector. A shift to better supply with fewer stock-outs is the best route to improving medicines access in this health system context; the supply of ARVs and TB medication free of charge by donor-financed programmes reflects this recognition (Mackintosh and Mujinja 2010).

It is interesting, therefore, that, in Tanzania in particular, a recent major shift in national policy focus towards industrial development has included a focus on rebuilding pharmaceutical production (URT 2016; 2015). Furthermore, this has been associated with sharply increased domestic funding commitments to purchase medication for the public sector. Thus the Tanzanian government has committed to greatly increase domestic funding for local procurement of essential medicines and health sector supplies, announcing a planned annual allocation of Tshs 251

billion (USD 112 million) for 2016-17 (BMI 2016a, 2017; and interviews), a huge increase on the previous year’s Tshs 80 billion. The Treasury has also repaid much of its debt to the national procurement body (Medical Stores Department, MSD), and the government has directly linked that funding commitment to objectives of local purchasing and industrial development, including increased domestic investment in MSD’s distribution infrastructure<sup>11</sup>. The Ministry of Health therefore, far from perceiving the national policy emphasis on industrialisation as competing with health care for tax funding, has embraced the scope for mutual benefit through increased local procurement. A mutual benefit lobby is emerging in Tanzania between health system actors anxious to reduce public supply shortages and arguing for higher public funding, and local industrialists looking for larger markets.

### Domestic procurement can improve responsiveness to local need

Can this collaboration work to benefit health? There are some reasons for positive expectations. First, from the industrial side, the limited data available suggest that public and non-profit procurement agencies already buy more locally than private wholesalers in the region. In Tanzania and Kenya, in 2013, a supply chain survey<sup>12</sup> found that for a sample of essential medicines (24 in Tanzania, 29 in Kenya), those sourced through private wholesalers were significantly less likely to have been bought from domestic manufacturers than those sourced by public wholesalers; the large faith-based wholesaler in Kenya (MEDS) was the most likely wholesaler in the survey to have bought locally. This was the case even though, at the time of the survey, very few medicines for HIV, malaria and TB, the main vertical programmes’ concerns, were sourced locally. Thus, more funding through these public and non-profit procurement bodies is likely to expand the market for domestic firms.

Second, from the health side, a case study of MEDS<sup>13</sup>, the Kenyan non-profit wholesaler, showed that it is possible to associate local procurement with a high level of responsiveness to local need. In interviews in 2013, faith-based Kenyan health facilities expressed considerable satisfaction with MEDS’ response to supply gaps and specific requirements, and rapid turnaround on orders. MEDS in turn attributed its performance in good part to flexible contracting with local suppliers based on an approved supplier list monitored for quality and delivery times. The public procurement body in Tanzania, MSD, is now

<sup>10</sup> WHO NHA database ([www.apps.who.int/nha/database/ViewData/Indicators/en](http://www.apps.who.int/nha/database/ViewData/Indicators/en)), consulted 06.05.17)

<sup>11</sup> Unreferenced statements in that sentence and the next summarise information from interviews with health sector key informants in Tanzania in 2017.

<sup>12</sup> Source: *Industrial Productivity* project, see note 8.

<sup>13</sup> Source: see note 13

putting more effort into building comparable interactive links with individual local suppliers<sup>14</sup>. In Kenya, the health care decentralisation reforms have devolved public procurement to the counties; the reforms aimed to improve responsiveness by the Kenyan public wholesaler, KEMSA (Kenya Medical Supplies Authority), to local needs. KEMSA is using framework contracts with local manufacturers to improve response times<sup>15</sup>.

Health system interviewees in both countries in 2013 and 2017 emphasised that shorter supply chains could and should enable more rapid and responsive supply to public health facilities. Interviewees also explained, however, that this outcome depended on much closer health-industry working relationships, including adaptation of contracting frameworks to address lead times, ordering, and payment schedules: in 2013, one non-profit wholesaler in Tanzania described difficulties it faced in buying from local suppliers that had resulted in *longer* lead times than ordering from India. MEDS' experience shows that these problems *can* be overcome, but they require detailed attention to individual suppliers' capabilities, well-designed contracting, and consistent communication with suppliers<sup>16</sup>.

Third, in terms of mutual benefits for industry and health sectors longer term, there is documented evidence<sup>17</sup> both of a resurgence of interest in pharmaceutical sector investment from local and international investors in the region, and also of some focus by new investors on gap-filling in response to identified and important national needs. The current active investment and proposals include creating more high-quality regional sources of combination antimalarial medication (ACTs) and of antiretroviral medication (ARVs) for HIV; also producing more key medication for NCDs including hypertension and diabetes; and increasing regional suppliers of intravenous drips and parenteral preparations. All of these items are currently

largely imported. Simultaneously, local investors in Tanzania have started to open production facilities for medical supplies such as bandages, in severe short supply, using locally produced inputs such as cotton.

#### Local production can improve rural access to medicines

Availability of and access to basic medication is consistently worse in rural as compared to urban areas, in both public and private sectors. Rural areas still contain much of the lowest-income population, and poor availability of medication arises from a combination of delivery difficulties and also lack of demand (and hence profit) due to very low incomes (Cohen et al 2010; URT 2014; Mackintosh and Mujinja 2010).

Small-scale surveys and qualitative evidence from Tanzania in 2008-9 showed that a high proportion of rurally available medicines had been made locally (Mackintosh and Mujinja 2010). Small sample survey data from 2013 confirm that, even in Tanzania where local manufacturing output had been falling, a significantly higher proportion of essential medicines used as tracers and found on rural shelves (in facilities and shops) had come from local rather than imported sources (see Table 2).

In Kenya, the effect was even sharper (see Table 2) and interviews also confirmed that local products were particularly distributed and favoured in rural areas. In Tanzania, distribution of imported subsidised combination anti-malarials was also found to be geographically patterned, with lower availability in remote areas (Cohen et al 2010). However, later evidence indicated that efforts to improve rural availability and use of these antimalarials, including rural subsidies in Kenya, had largely closed the gap in Tanzania, Uganda, and Kenya (Morris et al 2015; ACT Watch Group et al 2017b).



**TABLE 2. SOURCE OF TRACER ESSENTIAL MEDICINES AVAILABLE ON DAY OF VISIT, FACILITIES AND SHOPS, ALL SECTOR, BY RURAL/URBAN, TANZANIA AND KENYA, 2013 (% OF TOTAL BY RURAL/URBAN LOCATION).**

	TANZANIA		KENYA	
	LOCAL	EXTERNAL	LOCAL	EXTERNAL
RURAL	19.8	80.2	54.9	45.1
URBAN*	13.0	87.0	35.5	64.5

Source: Calculated from fieldwork data 2013. Tanzania n=646; Kenya n=1043.

\* In Tanzania, includes semi-urban areas on outskirts of cities and small urban areas in rural districts.

<sup>14</sup> Source : interviews 2017

<sup>15</sup> Source: interviews 2017

<sup>16</sup> Source: interviews 2013

<sup>17</sup> Sources for this paragraph: interviewing 2017; data collection 2013.

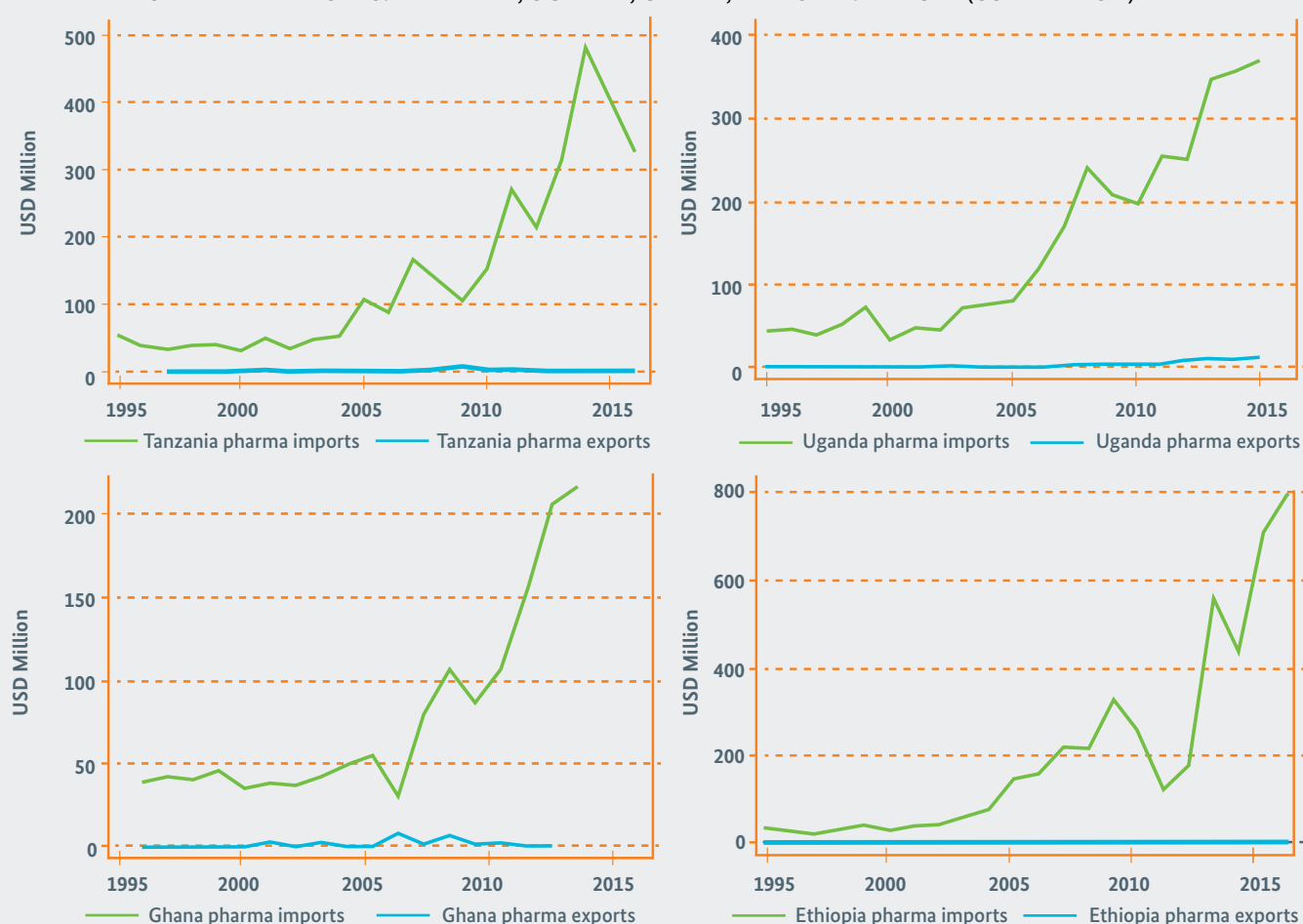
Finally, analysis of WHO/Health Action International survey data in Tanzania on medicines availability and source showed that, in 2006 and 2009, the probability of finding a locally produced medicine (from a larger set of essential medicines) was not significantly different in rural and in urban areas, while imported medicines displayed ‘urban bias’, that is, they were much more likely to be found in urban facilities and shops (Mujinja et al 2014). Initial analysis of 2012 data<sup>18</sup> confirms that this effect persisted in 2012, though with lower overall availabilities of local medicines because of the drop in local production noted above (see Table 1). Part of the explanation appears to lie in active distribution by local manufacturers, particularly, in 2006 and 2009, by Shelys and Tanzania Pharmaceutical Industries (TPI) using their own distribution networks as well as local wholesalers. In Tanzania, an exit survey at private and non-governmental organisation (NGO) facilities and shops in 2008 picked up public satisfaction with these local brands (Mackintosh and Mujina 2010). A managing director of another local manufacturer interviewed in 2017 recognised this distribution challenge: his firm was actively expanding both its in-house distribution capability and its brand recognition efforts. The implication of this evidence

is that local firms, relying on the domestic market for the bulk of their sales, have an incentive to support and extend availability of basic medicines in more remote and rural areas, while importers are unlikely to address this challenge and may need subsidies to do so.

### Health systems can benefit from close-to-market competitive suppliers when external buyers open market access opportunities for Africa-based firms

The very large rise in development aid for the purchase of medicines (see above) has greatly enlarged the medicines markets in East Africa. While trade data do not necessarily capture all externally funded medicines, Figure 1 shows the scale of net imports (the gap between the top line, imports and the lower, exports) in Tanzania, Uganda, Ethiopia and also, for comparison, Ghana in recent years. The expanding gap represents a source of serious health security concern for the medium term, since the imports require sustained hard currency funding and imply reliance on Indian exporters who may not be committed to African markets in the longer term (Chaudhuri et al 2010); the gap also indicates the market opportunity for local manufacturers.

➔ **FIGURE 1. PHARMACEUTICAL IMPORTS AND EXPORTS: AFRICAN COUNTRIES WITH RAPIDLY RISING IMPORT LEVELS AND FEW EXPORTS: TANZANIA, UGANDA, GHANA, ETHIOPIA: ANNUAL (USD MILLION)**

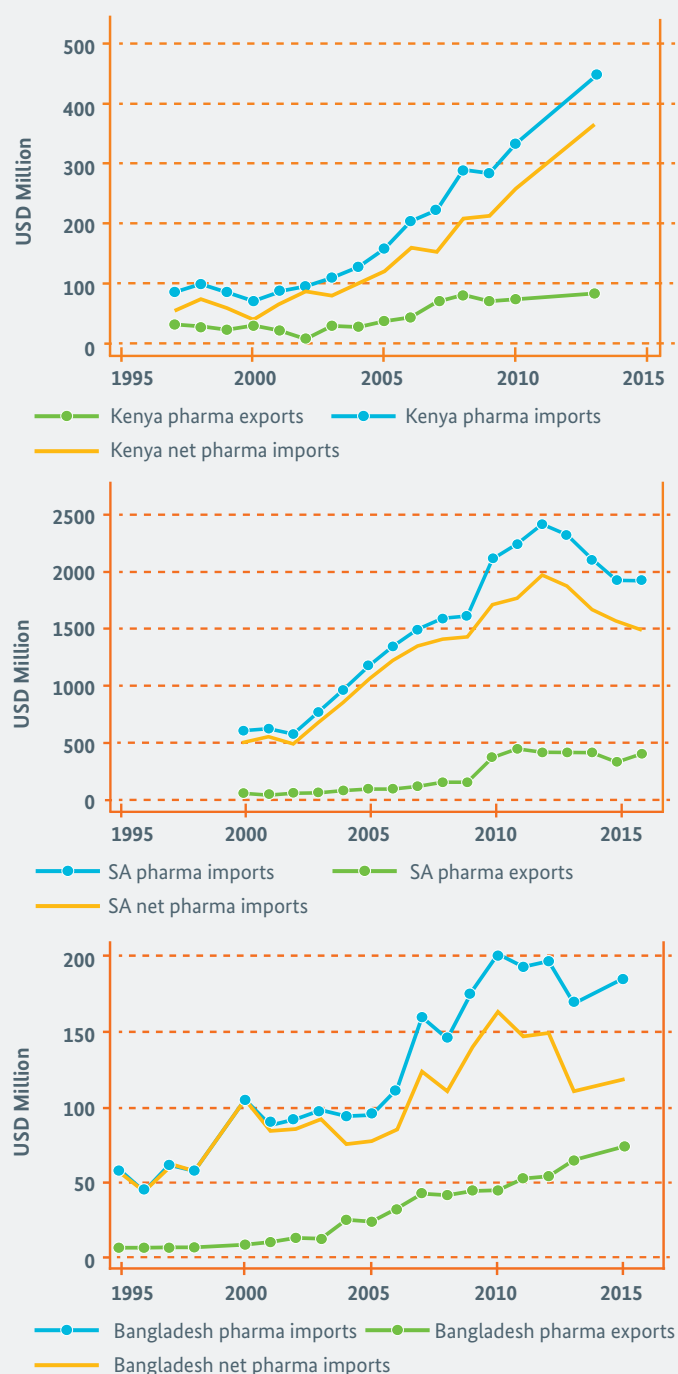


Source: Comtrade data (<http://comtrade.un.org/data/>), downloaded 5.8.14).

<sup>18</sup> Source: Ongoing work with Marc Wuyts and Mary Justin-Temu; initial finding used with permission.



**FIGURE 2. PHARMACEUTICAL IMPORTS AND EXPORTS AND THE PHARMACEUTICAL TRADE BALANCE: COUNTRIES WITH SUBSTANTIAL EXPORTS: KENYA, SOUTH AFRICA, BANGLADESH: ANNUAL (USD MILLION)**



Source: Comtrade data (<http://comtrade.un.org/data/>, downloaded 5.8.14).

There is therefore widespread African concern about the scale of this import- and donor-dependence (see Figure 1). Even countries with stronger industries and substantial exports, such as South Africa and Kenya, have a large net import 'gap' (see Figure 2). Elsewhere, Bangladesh is a notable example of a country which has built up a local pharmaceutical industry and is achieving consistently rising exports and apparently stabilising import totals (see Figure 2).

The net imports in East Africa are largely externally funded, either through vertical programmes or via support for governmental and NGO medicines procurement. Currently, this procurement is almost entirely from manufacturers in India, China or high-income countries, and the failure to 'buy local' has reduced market access for East Africa-based firms. The switch to combination antimalarial medication for first-line treatment in Tanzania, subsidised and supplied from India, caused large business losses to local producers of the previous first-line treatment, one firm losing an estimated one-third of its turnover<sup>19</sup>. The subsidy to public and private ACT prices has made the medication much more accessible for the population (ACT Watch Group et al 2017b), but has undercut the viability of direct market supply by local firms: the market is dominated by a few major international purchasers for subsidised distribution.

Until recently, it would be fair to say that most officers of large global funders – philanthropic funds, governments and large NGOs – have seen this issue as irrelevant to their concerns. As one interviewee from a large buyer put it<sup>20</sup>, he prefers 'single sourcing, lowest price, economies of scale'. This has been a widely held view (Wilson et al 2012), underlying commitments to pooled procurement at international level and to very large tenders with the aim of driving down procurement prices. There are understood limits to the extent to which scale can drive down price (Waning et al 2010). Nevertheless, this approach to procurement is generally justified on the grounds of maximising the numbers treated with medication for HIV, malaria and tuberculosis<sup>21</sup>. Recently, however, the approach has been shifting. There is recognition, in the words of a philanthropic procurement manager, that there is no benefit in creating monopolies by driving prices down to the point where many suppliers leave the market. Nor is it possible to ignore the strongly expressed African concerns about the local industrial implications (see above).

<sup>19</sup> Source: Interviewing for Mackintosh M and Mujinja PGM (2011) *Interactions between Global Policy and Local Markets and Production of Medicines: a case study in Tanzania* Report to UNITAID, unpublished.

<sup>20</sup> Source: interviews 2017

<sup>21</sup> Source: Interviews 2017, see also Wilson et al (2012).

<sup>22</sup> Information from The Global Fund cited with permission.

As a result, policies of large external buyers are being adapted<sup>22</sup>. Both PEPFAR and the United Nations International Children's Emergency Fund (UNICEF) were said by interviewees to take a flexible approach to buying from local manufacturers<sup>23</sup>. The Global Fund is also developing more local purchasing. The Global Fund's guiding principles are value for money, quality (WHO-prequalification) and sustainability, which means affordability: it will not subsidise firms. However, The Global Fund procurement system now works actively with potential African suppliers to assess their capabilities and potential. They recognise that the small number of Africa-based firms with products pre-qualified by the WHO have found it difficult or impossible to win tenders against competition from large Asian suppliers. Yet African manufacturers cannot improve, learn, invest and reduce costs unless they can sell, so where the externally funded market is dominant, the barriers to market entry have become very high. The Global Fund has also identified health system benefits from local supply, in particular proximity to market, resultant short lead times and responsiveness, and diversification of competitive sources of supply over time.

For prequalified firms, The Global Fund therefore now uses a broader definition of value, called 'total landed cost', which includes points for shorter supply times than importers can achieve. Firms can develop their scores on the basis of advantages of proximity and include those in their tender. On this basis, The Global Fund is buying long-lasting insecticide-treated bed nets from A-Z, the large Arusha-based (Tanzania) manufacturer with good regional communications and logistics and much lower transport costs for a bulky product; it is also buying ACTs from CIPLA Quality Chemicals in Kampala. Furthermore, The Global Fund's tenders are never 'winner takes all': the aim is to ensure a range of suppliers, not monopolies. Tender prices accepted will vary within one tender, so the tender outcome sets a 'reference price' for the particular item, and then a single price paid by each country from its allocation, which is never above the reference price.

The implication of this procurement strategy towards local manufacturers is that there is scope for other funders to support complementary efforts at quality enhancement by Africa-based manufacturers to meet global standards 'as the Asian suppliers have done'<sup>24</sup>. The Global Fund accepts that this is a 'journey' for the Africa-based firms. The Global Fund will work with potential suppliers by making suggestions for reducing costs, e.g. by finding cheaper inputs, and collaborate with other funders by, e.g. providing market data. German and Japanese assistance in particular

is playing a major complementary role in technology and quality upgrading. For the firms, Global Fund contracts are thus 'the carrot at the end of the journey'.<sup>25</sup> For the health system, by implication, the journey is towards an efficient, diverse and competitive supplier base for essential medicines and health commodities that is sustainable over time.

### **Improved regulation of quality can benefit both industry and patients**

It follows from the above discussion that quality assurance in manufacturers is a central win-win for both industrial suppliers and health systems, generating market access and safe medicines. The essential underpinning of quality assurance is provided by effective regulation. For the industrialists, good regulation provides, first, stimulus and pressure to attain safe recognised quality standards, and second, entry to markets for quality assured medicines. For health systems, effective regulation of local manufacturing ensures that locally sourced medicines and supplies – already widely used – are of reliable quality.

Regulation, furthermore, is necessarily a shared enterprise: it involves a complex mix of standard setting, inspection, enforcement, advice and support to meet standards, checking of procured supplies, post-market vigilance and following-up of complaints. Manufacturers and health system actors are in agreement that external support for regulatory improvement, at both national and East African regional level, has been central in reducing the incidence of sub-standard and counterfeit medicines in the private market, and in contributing to upgrading of quality across the local industry towards Good Manufacturing Practice (GMP) standards. External agencies including UNIDO, the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), PTB (Physikalisch-Technische Bundesanstalt – Germany's national metrology institute), WHO, Drugs for Neglected Diseases (DNDi) and the World Bank have supported regulation and hence manufacturing improvement across the region.

All manufacturers interviewed, in 2013 and 2017, in Tanzania and Kenya, were working on upgrading and improving their quality assurance systems. New investors coming in are now looking to start with internationally recognized GMP manufacturing standards<sup>26</sup>, and in order to assist local firms and investors, Kenya has developed the first of several regional roadmaps for upgrading local firms to achieve international GMP standards. Good regulation supports joint venture development and technology transfer: one respondent from a multinational corporation

<sup>23</sup> Interviews in Nairobi 2017 and in Dar es Salaam 2015.

<sup>24</sup> Global Fund interviewee, 2017

<sup>25</sup> Source: Interviews 2017: cited with permission

<sup>26</sup> Source: Interviews 2017



with operations in Kenya stated that they were 'aware of some of the key weaknesses of local pharma, for example around quality assurance and quality inspection procedures, and would not want to put their reputation at risk'. The region, however, still lacks infrastructure such as sufficient high-quality reference laboratories for regulatory work, and needs a stronger scientific and technical base to support these institutions. Regulatory effectiveness is uneven across the East African region, with Tanzania generally recognised as having the strongest regulator. External support for regulatory harmonisation initiatives across the East African region, to reduce the regulatory complexity of intra-regional exports, is widely appreciated by manufacturers and regulators, and NEPAD's Africa Medicines Regulatory Harmonisation (AMRH) is providing such a development platform. For local regulators, the regulation of local firms is in principle both simpler and more reliable than for external suppliers. Local firms can be visited regularly; Indian firms only once every three years. However, there are complexities: regulatory 'capture', whereby regulation is weakened by political and financial influence, is an issue across the world. Supporting effective independent regulators of local suppliers is one of the most useful roles for external actors, benefitting both the health and industrial sectors.

#### **Sustaining domestic competition can lower costs and prices over time**

The most common accusation levelled at local manufacturers in African contexts is that they are not competitive: that their costs are too high, and scale and technological capability too low (Wilson et al 2012; Kaplan and Laing 2005; Mohamed 2009; Rovira 2006; Seiter 2005), and that, as a result, a shift to local manufacture implies higher prices for patients. There is no doubt that African manufacturers suffer cost disadvantages, notably because of poor-quality but costly infrastructure such as power, water and transport. In basic formulations – making pills and tablets – economies of scale are not large, but African manufacturers have to import all their APIs in smaller quantities and at higher cost than competing Indian and Chinese exporters. However, the African manufacturers also have the advantage of proximity (their costs reduced by shorter supply lines) and knowledge of the domestic markets. Medicines prices fluctuate, and direct comparison of the prices of local and imported essential medicines is difficult and produces variable results. The local private markets tend to be quite competitive for basic items (Mackintosh and Mujinja 2010), and local manufacturers can meet competition by accepting lower margins than those earned on imports (Chaudhuri and West 2014).

If local manufacturing is to flourish, some relatively small level of consistently applied trade protection is required while the industrial sectors develop. It takes a long time to develop local industrial capabilities and efficiencies to meet international competition, as the AUC's 50-year development plan for Africa (Agenda 2063) recognises. 'Infant industry' development is a well-recognised argument for protection, since it gives firms competitive breathing space to improve capabilities (Sutton 2012; West and Banda 2016). The Indian government continues actively to support its pharmaceutical industry including export support. East African countries have therefore generally been offering for some years a price premium for public procurement: a percentage price uplift acceptable for a local tender as compared to imports. In Tanzania and Uganda this is 15%; in Kenya it varies from 10% downwards according to level of local ownership. However, in Kenya and Uganda interviewees said it had not been consistently applied in the past. In addition, other forms of protection are now under discussion, despite the zero common external tariff in the EAC. Uganda has applied a 2% verification fee on imports which may be raised to 12%. Tanzania is discussing a list of products for local public procurement only, rather than external tender. Kenya has a draft Trade Facilitation Act that would allow complaints by local firms alleging dumping by external suppliers. Dumping of finished formulations below API cost is a genuine concern, with cases of apparent dumping documented by manufacturers.

The main constraint on price increases in the domestic market is supplier competition, and it is essential to maintain domestic competition. What is sometimes called the 'Ghana model' of pharmaceutical industry promotion seeks to combine a market protected by blocking imports of basic items that can be produced locally with the active promotion of a growing and competitive domestic industry. Ghana has had a short list of medicines for local supply only, and has very recently expanded that list to 49 medicines, using a gazette Executive Instrument 181 (E.I. 181), dated May 10, 2017<sup>28</sup>. The banned medicines include antibiotics, analgesics, oral rehydration salts and multivitamins, and the Food and Drugs Authority (FDA) of Ghana will not accept new registrations of the medicines on the banned list. Ghanaian industry has received domestic support and external support (West and Banda 2016; BMI, 2016b). The extent to which local production can deliver falling prices over time depends strongly on local context. In Bangladesh, domestic manufacturing has been associated with low prices but variable quality (Ahmed et al 2013). In Africa, ensuring market competition in the context of effective regulation will be the key to mutual industry-health benefit.

<sup>27</sup> Source for unreferenced statements in this paragraph: interviews 2014 and 2017

<sup>28</sup> [www.graphic.com.gh/news/general-news/no-more-import-of-49-medicines-local-manufacturers-to-fill-gap.html](http://www.graphic.com.gh/news/general-news/no-more-import-of-49-medicines-local-manufacturers-to-fill-gap.html), accessed 10 June 2017.

### Investments in pharmaceutical training can benefit both health systems and industrial suppliers

Skills and training are the missing win-win: all sides emphasise and document the need for major improvement, but the commitments and therefore evidence of benefits remain thin. Interviewees agreed across the health-industry divide that skills development and training were central to addressing their needs, and that the industrial and health needs overlap in pharmaceuticals. Health system strengthening is widely agreed to need more effective pharmaceutical management, including supply chain management and procurement practices, but the systems lack the trained staff to achieve this (Wiedenmayer et al 2015; Yadav 2015; Waako et al 2009). In 2013, 53% of Kenyan and 73% of Tanzanian health facility interviewees responsible for ordering had no training, short courses included<sup>29</sup>. The frontline health systems also need competent laboratory technicians. Nationally, medicines policy and management for health needs excellent clinical pharmacists and pharmacological scientists.

Many of these training needs overlap with the needs of industry, and industrial pressure allied to a commitment to industrial development can generate support for enhanced pharmaceutical training. Interviewees identified pharmaceutical technicians as a large shared gap. Industrial laboratories also find it hard to recruit and retain skilled staff, who have to be trained on the job and are in short supply. Interviewees argued for a rethink of pharmacy teaching at tertiary level to include industrial skills and experience. The pharmaceutical industry particularly needs industrial pharmacy and chemical engineering training (Ministry of Health 2016), as well as biochemistry, microbiology, biomedical engineering and other allied sciences. Across the region, some tertiary institutions are introducing industry attachments, but much more is needed to generate the technical and scientific base for industrial growth. The need is particularly great in Tanzania, and is a real constraint on industrial development (MIT and UNIDO 2012). Pharmacy specialisms include industrial pharmacy, clinical pharmacy, drug designing and formulation; every level – pharmacy assistants (Certificate), pharmacy technicians (Diploma) and degree level – is needed in both health and industry.

Medicines policy and regulation link health and industry and also require major improvement in the pool of technically and scientifically trained people in all pharmaceutical specialisms with an ability to work across the health-industry divide. As the head of one professional association put it, there is a need to ‘cook our own food’: professionalism and good regulation are central. Regulation of a knowledge industry such as pharmaceuticals is underpinned by science, technology and innovation; medicines policy is underpinned by clinical skills; and the two need to work together locally. The Science Technology and Innovation Strategy for Africa (STISA 2024) speaks to this realisation. Regulatory and quality assurance laboratory skills are being built through initiatives such as U.S. Pharmacopeial Convention (USP) Ghana’s Center for Pharmaceutical Advancement and Training (CePAT) through a block release programme. In Southern Africa, collaborative efforts in regulation and skills training are being co-developed through the ZAZIBONA (Zambia, Zimbabwe, Botswana and Namibia) initiative, which matches experienced with inexperienced regulators in joint inspections across the four countries, to raise skills levels and feed into NEPAD’s AMRH programme. Industry and health benefit from faster turnaround, harmonisation of standards and better quality assurance. Skills inadequacies do not only impede these ends, but, as one Kenyan respondent noted, they ‘also leave the few and over-stretched professionals available vulnerable to manipulation through corrupt practices’. Health and industry share a need for a stronger, better-skilled cadre of professionals, with clear career paths.

<sup>29</sup> Source: *Industrial Productivity* project, see note 8.

<sup>30</sup> Interviews in Nairobi 2017

# Emergencies, pandemics and medium-term health security: global and local priorities

When a health system is challenged by emergencies or pandemics, its strength and resilience are demonstrated by its ability to ensure the health security of its citizens against the threat. The opening reflection identified some differing priorities between African health professionals and the 'global' health literature when emergencies and pandemics are addressed. No African health professional underestimates the dangers of haemorrhagic viruses such as Ebola. Rather, African professionals' experience is of coping constantly with recurrent lethal emergencies in struggling, under-staffed and underfunded health systems. Policy makers and industrialists interviewed about medium-term threats to health security emphasised rising NCDs such as diabetes, hypertension and cancer: the African Union's Agenda 2063 emphasises the health implications of demographic shifts as young populations age.

African and 'global' perspectives on emergencies and health security do not necessarily conflict. They do, however, generate distinct approaches to local health-industry linkages in African contexts, and to timelines in addressing local health security. Differences revolve around priorities for immediate improvements in local health security, especially in strengthening ability to cope with emergencies, and also around medium- to long-term priorities for sustainable and resilient strengthening of national health security in Africa in the face of both infectious and NCD burdens. Global health initiatives can benefit from much clearer specification of time perspectives: short-, medium- or long-term perspectives each require different tactical and strategic focus, especially when viewed through the combined lenses of socio-economic development, local health security, and generating local scientific-industrial-health linkages to build sustainable and resilient local health systems.

## THE GLOBAL HEALTH FOCUS HAS LEVERAGED RESEARCH AND DEVELOPMENT TO CREATE A PIPELINE FOR NEW VACCINES AND TREATMENTS

The concept of global health security underpins the current framework for global preparedness and response to emerging infectious diseases (Flahault et al 2016). The receptivity of the foreign policy and security communities to health aspects of security has a history that goes back to the Cold War and the shift in threats from nuclear to biological sources. The 'security language' increasingly used by global public health actors may, therefore, effectively have increased political attention and resources for global health issues (Elbe 2010; 2011; Rushton 2011; Rokvic and Jeftic 2015). The Global Health Security Agenda focuses on 'strengthening capacities for detection, response and prevention' (Flahault et al 2016). In this field the global health focus, for both high income countries and African societies, has been research efforts that have leveraged product development partnerships to produce a pipeline for new vaccines and treatments.

This effort, which has been an investment in solidarity as well as security, has the potential to save large numbers of lives. Product Development Partnerships (PDPs) such as the Malaria Vaccine Initiative (MVI), International AIDS Vaccine initiative (IAVI) and Medicines for Malaria Venture (MMV) have been generally well funded, and have enriched the product development pipeline for therapies that address health challenges for Africa. By garnering a critical mass of resources for research and development, PDPs have sharply reduced the risk involved in translating new medical technologies into treatments, by bridging the so-called 'valley of death' between research and application. As a result, they have greatly increased the chances

for emergence of new therapies and promising treatments which would otherwise not have been possible without this type of innovative organisational setup. A number of the interventions, although not yet in the clinic, are in clinical trials. This has had the effect of improving clinical trial design and local trials management skills and capacity. Broadening or localising the therapy development innovation pathways and technological capability building would call for inclusion of African vaccine organisations in the research and development activities by the PDPs where possible.

African policy actors acknowledge the scale and importance of global health efforts, just as many global health commentators are aware of limitations that include a perceived privileging of containment over prevention of infectious disease (Aldis 2008; Rushton 2011; Flahault et al 2016). The dangers of haemorrhagic viruses are actively addressed by East African public health professionals. Tanzania, for example, implemented active port and border surveillance during the Ebola outbreak, picking up some suspected (negative) cases (WHO 2017c). To address technological capability building, initiatives such as the African Vaccine Manufacturing Initiative (AMVI) and the African Network for Drugs and Diagnostics Innovation (ANDI) aim to enhance local development activities by working with industry and research institutions respectively.

## **AFRICAN HEALTH ACTORS PRIORITISE IMMEDIATE EMERGENCIES AND HEALTH SYSTEM RESILIENCE**

African interviewees for this Brief consistently reacted questions about response to emergencies in two ways: first, by enumerating other recurrent, life-threatening emergencies that their health systems were still struggling to deal with, and second, by emphasising the importance of broad health system capabilities and resilience in being ready to address pandemics and crises.

Tanzanian and Kenyan lists of emergency priorities were very similar, particularly identifying emergencies of haemorrhage and dehydration. Failures to stop bleeding in childbirth, for example, because of a lack of anti-haemorrhage drugs, is responsible for many deaths, and lack of immediately available intravenous (IV) fluids prevents rehydration, particularly of young children. These gaps in the supply chain of essential inputs are further thrown into relief by cholera epidemics, such as that in Tanzania in 2015. These inputs are all imported in Tanzania, though there are Kenyan and Ugandan IV manufacturers. Local firms find it hard to match external prices for IV fluids; however health security concerns are driving efforts to develop and ensure a market for local production of

IV fluids to ensure shorter supply lines and faster gap filling of these emergency supplies. These efforts include active technical support and monitoring for 60 hospitals to make their own IV fluids by a team at St Luke's School of Pharmacy in Tanzania<sup>31</sup> which has been supported by German technical cooperation. Kenyan interviewees also said that Universal had been able rapidly to supply low-cost and effective oral rehydration salts to some African countries in the last few years to tackle outbreaks of diarrhoeal diseases.

Further causes of deaths in emergencies are lack of antibiotics such as penicillin. Tanzania has been losing local antibiotic production capability (Tibandabage et al 2016a) and does not produce injectables, though there are Kenya-based firms with this capability. The public procurement agency in Tanzania is trying to diversify its suppliers of basic antibiotics, and to ensure availability of local suppliers in a crisis. Lack of anaesthetic drugs for surgery, adrenaline for allergy cases and medication for asthma are all important causes of emergency deaths. There was unanimity among the Tanzanian health sector interviewees that local manufacture of these items would potentially improve local health security by adding new close-to-user suppliers.

Asked how emergency preparedness could be improved, Tanzanian interviewees emphasised the need to tackle unavailable supplies within the country. Kenyan interviewees, however, in a country with a much larger industrial base, particularly emphasised health sector organisation, logistics and distribution capability as key aspects of effectively accessing emergency supplies and making them available in a timely manner. They also picked up issues of laboratory capability, quarantine preparations, border control, records management and decision making. These responses echo an emerging view in the global health literature that pandemic preparedness centrally includes the strength and resilience of local health systems. Kenyan interviewees also saw lack of capability to tackle neglected tropical diseases as a further emergency issue. They noted that Kenya had the manufacturing capability it could build on: now it needed to improve the ability of the health system to use those capabilities in crises.

## **LOCAL MANUFACTURING BRINGS TECHNOLOGY AND EXPERTISE TO SUPPORT AFRICA'S MEDIUM-TERM HEALTH SECURITY**

Does geography, i.e. the location of expertise and manufacturing capability in pharmaceuticals, matter for health security? African interviewees all argued that it does: that national governments are responsible for national health security and that, in this regard, national technological

<sup>31</sup> Source: interviews 2017

and scientific expertise is essential. African governments and inter-governmental bodies such as the EAC, AUC and NEPAD are all looking for ways to enhance local skills and capabilities, and many policy makers perceive manufacturing as a focal point for building improved security medium term.

While most SSA pharmaceutical manufacturing consists of basic formulations using imported APIs, there are signs of a rising technological level, bringing with it the required scientific and technical capabilities. Scientists and manufacturers are looking for niches where API manufacturing can get started. Economies of scale are much more important in making APIs than in formulations, so it is hard for a smaller-scale producer to compete; it follows that potential market niches include low-dose APIs where the main market is in Africa, such as Entecavir for Hepatitis B (Fortunak et al 2016). Fine Chemicals in South Africa, which has benefitted from government support, produces a number of APIs, and in Ghana La Gray has a small capacity for manufacturing an antibiotic (azithromycin) (Fortunak et al 2016).

More broadly, joint ventures, technology transfer and external technical and funding support are shifting the manufacturing base towards more complex products and processes. The joint venture that created CIPLA Quality Chemicals brought technology, technical and management skills and products to the Uganda plant. The buyout by Strides of a majority holding in Universal in Kenya has brought new products to the Kenyan plant<sup>32</sup>. In Ethiopia, the Sino-Ethiopian joint venture exporting hard capsule shells across Eastern and Southern Africa has transferred skills and technology effectively to the Ethiopian partner and staff<sup>33</sup>. New investor proposals in Tanzania aim to address the gap in local supply of formulations for NCDs and ACTs, and expanding the regional base of ARV production. DNDi has supported upgrading of one firm to produce high-quality combination antimalarial tablets<sup>34</sup>. In Tanzania a Cuban-Tanzanian government joint biotechnology venture began in 2015 to use Cuban technology to produce biolavicides to control mosquitos; trials are currently underway. In an unprecedented move, Biovac has transferred technology to Indonesia and Japan for a locally developed human papillomavirus (HPV) vaccine, showing scope for technological capability export from the continent.

Recently, Biovac signed an agreement with Sanofi for the production of the Strep B Group vaccine. Effective transfer of technology and innovative expertise to local staff, to generate technological learning, is key to the impact of these investments for the health system, ensuring both their sustainability and a build-up of key skills within the country.

These innovation and skills-building processes are important for emergency preparedness. As a Kenyan interviewee pointed out, the issuing of compulsory licences to manufacture depends on local production capabilities – and in a crisis there is also legal scope to supply other neighbouring countries without the relevant capacities. The use of TRIPS flexibilities is also open to manufacturers in the region, including Kenya (Ogendi 2013), but a Kenyan interviewee argued that their use is being blocked by a fear of litigation by originator companies, and by companies' lack of full awareness of Kenyan legislation to permit compulsory licencing.

## LOCAL VACCINE PRODUCTION IS CHALLENGING, BUT HAS PAYOFFS FOR HEALTH SECURITY

The incentive to build up national and SSA regional capabilities is particularly strong in pandemic medication and vaccines, where national security is threatened, given the widely held assumption that in a global pandemic, high-income countries will treat and protect their own populations first. Vaccines and immunisation programmes are key components of saving lives and strengthening health systems. However, virtually all vaccines used in Africa are imported (USD 1.2 billion in 2013), since the five key manufacturers produce only 1% of requirements. According to the Vaccine Manufacturing and Procurement in Africa Study (AVMI/UNIDO/WHO, no date), in Africa 37 countries procure all vaccines through UNICEF, and Africa's share of UNICEF's total procurement is around 60%. Senegal's Institut Pasteur Dakar produces a WHO-prequalified yellow fever vaccine, while South Africa's Biovac (a local public/private partnership) is engaged in late-stage vaccine development while currently producing vaccine vials using imported APIs.

<sup>32</sup> Source: Interviews 2017

<sup>33</sup> Source: Visit and interviews 2015

<sup>34</sup> Source: Interviews 2014 and 2017



Vaccine manufacturing development is particularly challenging because of high levels of global competition from large producers, and high levels of pooled purchasing by UNICEF with development aid funding. The largest funder is the GAVI Alliance<sup>35</sup>, which generally requires UNICEF procurement for its funded vaccines (ibidem). However, the AVMI study put health security at the top of the list of reasons for exploring the scope for a shift in manufacturing capability to Africa, followed by addressing specific and unmet needs and pandemic preparedness (ibidem).

Vaccines are risky products with high barriers to market entry and long lead times for product development. However the same study argues that there is potential for local production in the next 10 to 20 years, given projected population growth. It suggests that regional hubs are likely to be the best strategy, but they require political and technical support, an area of advocacy and technology addressed by AVMI.

Vaccine and biological production is thus at the high end of the challenges for local production. Investment of USD 60-100 million is required to set up a manufacturing facility (ibidem), but the payoffs in terms of both skill level and medium-term national health security are also high. Moves towards expansion of vaccine manufacturing would build on developing biological product manufacturing and also clinical trials experience which is extensive in South Africa. Initiatives would require technology transfer, e.g. through joint ventures; current experience also suggests the need for government and philanthropic support. Regulatory capability would need to be built up, and local procurement and funding developed. The African Vaccine Regulatory Forum (AVAREF) is active in this area.

<sup>35</sup> We did ask the GAVI Alliance for an interview to discuss local production of vaccines but they declined.

# Policy implications: how external actors can support local health-industry synergies

## LINKING THE POLICY SILOS

Many external agencies already work on both sides of the health-industry divide, and some are now trying to link up the policy silos. The WHO has deep involvement in industrial technology and regulation in pharmaceuticals as well as leading international work on UHC. German development cooperation has a strong track record in both health system strengthening and industrial development in Africa. From the evidence presented, the following stand out as areas where external actors can usefully extract synergy from linking their activities, or can reach out to other actors across the policy divide to support an upward spiral of mutually beneficial local health-industrial linkages in Africa.

## SUPPORTING INCREASED MEDICINES ACCESS THROUGH PUBLIC AND NON-PROFIT SUBSIDISED ROUTES

Development funding for quality assured medicines has made a crucial contribution to saving lives. Across East Africa these medicines are generally made available free of charge to ensure maximum access, the main exception being subsidised ACTs for private distribution. More broadly, in African contexts medicines procured through non-governmental non-profit and public procurement are consistently of better quality than private market medicines, and are also more affordable. Finally, stock outs and leakages to the private sector from public systems are one of the major constraints on access to medicines.

It follows that external support for a wide variety of 'socialised' routes to medicines access is likely to improve the inclusiveness of health systems with respect to medicines

access and the objective of UHC. A shift in access routes away from private markets purchase is also beneficial since these markets still contain a higher share of sub-standard and counterfeit items than the public sector does. To leverage more local benefit the challenge is to link up different externally supported initiatives to expand and improve public and non-profit procurement and distribution of medicines, on the one hand, to initiatives for more effective local purchasing of medicines by public and non-profit procurement bodies, whether national or international, on the other hand.

## STRENGTHENING LOCAL PROCUREMENT AGENCIES AND PROCUREMENT LINKAGES WITH LOCAL FIRMS

Local public procurement agencies work in difficult environments, often with uncertain and erratic funding both locally and externally, and under conflicting pressures. They have also displayed a mixed record in terms of probity, efficiency and effectiveness. External agencies are working to improve delivery. In that context, supporting development of local competence in local purchasing offers a route to improvement of response times, as well as local industrial benefits. The MEDS example showed that working closely with local firms can create more flexible and responsive supply, and provide incentives for both sides to strengthen quality assurance, communication and contracting skills.

International procurement agencies are, as shown above, working on ways to engage with local suppliers. These more open procurement practices by externally funded programmes are welcomed by local manufacturers and promise a more diverse and sustainable supplier base for

medicines procurement for local health systems. The level of flexibility given by external funders to procurement agents varies, however, with different levels of openness to working with local producers. More consistent support by funders for external agencies' local purchasing initiatives promises substantial local benefits by making local health system supply chains more robust over time.

## **STRENGTHENING REGULATORY PERFORMANCE AND HARMONISATION**

Closely allied to procurement support is the need to support and strengthen the capability of national regulatory agencies, help them to sustain their skills, experienced staff and political autonomy, and to improve their equipment, procedures, enforcement and decision-making powers. African initiatives to build national regulatory skills and to strengthen national regulatory authorities have received substantial external support, and, as argued above, regulation is the key to quality improvement in the health sector and within manufacturers.

In 2017 interviews, one of the most appreciated forms of external support was at the regional EAC level for moves towards regulatory harmonisation, including shared guidelines, improved information systems, and moves towards shared inspections and product registration and approvals<sup>36</sup>. Market integration providing easier access by local manufacturers to regional markets is a route to lower-cost and more efficient local supply. From the health sector point of view, the payoff to improved regional regulatory performance is more availability of assured quality local products. Experienced and skilled local regulators can ensure incentives and pressures for upgrading to GMP standards while avoiding industrial collapse. Local interviewees identified policy silos that can be usefully integrated to improve regulatory performance, e.g. in Kenya, linking joint inspections and product approvals to the GMP roadmap. External actors can play a role in identifying problems and conflicts among related initiatives, and finding scope for compromise and synergy.

## **STRENGTHENING TECHNOLOGICAL UPGRADING AND QUALITY ASSURANCE**

Regulatory requirements for market entry are the single most important incentive to raise standards. However, local firms struggle to achieve the major improvements required to meet GMP standards and WHO prequalification. Key challenges include investment funding for new plants

and equipment. Local African initiatives to tackle this include work by the AUC and NEPAD with the Federation of African Pharmaceutical Manufacturers Associations in a Technical Working Committee to set up a Fund for Africa's Pharmaceutical Development (FAPD)<sup>37</sup>. External agencies can support initiatives such as FAPD to provide long-term capital for the industry to develop and produce quality assured medicines.

However, firms interviewed in Tanzania and Kenya did not see finance as the most important hurdle. Infrastructural support, including land, water and power connections, was strongly appreciated. But firms' central concerns were technological and organisational. Technical assistance, such as that provided by German and Japanese development cooperation, and also by WHO, is a key resource to allow firms to meet quality standards. A number of the most successful local manufacturers are joint ventures incorporating technology transfer, and external actors can play a role in bringing local firms together with potential commercial partners. In the EAC, German development cooperation is working with UNIDO and the German metrology institute PTB to support infrastructure for improving quality, including laboratory upgrading, and supporting the improvement of National Standards Bureaux. They have been helping to set up chemical reference standards, improving post-market surveillance, and supporting proficiency testing in laboratories. This type of quality-focused support for upgrading contributes strongly to both industrial and health agendas.

## **SUPPORTING SUSTAINED IMPROVEMENTS IN SCIENTIFIC, TECHNOLOGICAL AND INNOVATION CAPABILITIES**

Technological upgrading is not a one-off, but a continuous process. To underpin and sustain an improving industrial sector and support innovations in health care, African countries need to grow and sustain scientific, clinical and innovation capabilities in universities, government, regulatory agencies and industrial firms. External support can help to achieve this, in particular by working with local initiatives, directly or through public-private partnerships. The example of Biovac, above, is one indicator of the pockets of scientific and technological excellence on the continent that can be effectively supported by external assistance. Interviews in Kenya in 2015, as well as discussions with vaccine manufacturers in 2016 and 2017, all highlighted innovative, forward-looking international procurement and assured market access as key catalysts for continuous investment in innovative capabilities by local firms.

<sup>36</sup> <http://documents.worldbank.org/curated/en/578521468261309041/text/PID-Appraisal-Print-P155163-01-11-2016-1452524510362.txt> and interviews 2017

<sup>37</sup> [www.au.int/web/sites/default/files/newsevents/workingdocuments/32187-wd-rev\\_of\\_sa19094\\_e\\_original\\_position\\_paper\\_on\\_establ\\_of\\_fap-d-clean.pdf](http://www.au.int/web/sites/default/files/newsevents/workingdocuments/32187-wd-rev_of_sa19094_e_original_position_paper_on_establ_of_fap-d-clean.pdf) accessed 11 June 2017

## SUPPORTING AND ENCOURAGING MAJOR IMPROVEMENTS IN SKILLS AND TRAINING

Skills and training in pharmaceutical fields were argued above to be a core, yet still neglected need for both health and industry: many relevant policy documents fail to address the pharmaceutical skills gap that constrains both health system and industrial performance. Expert pharmaceutical commentators and representatives of professional bodies emphasised that skills were a long-term investment that was being neglected across the health and industrial sectors. The government, one interviewee emphasised, should be defining the skills needed and providing scholarships now to send people abroad to train in the higher-level specialisms. There is frustration that health and industrial investment strategies are missing the key element of investment in people. Missing skills that could be developed with external support include procurement and pharmaceutical management skills in the health sector, given the severe shortage of expert pharmaceutical staff in health facilities and logistical roles to support better medicines access.

External support is also needed for the whole range of industrial pharmacy and related skills, including management and GMP-related production control capabilities for quality assurance, and formulation and laboratory qualifications. Where investments have been made, they need be fully exploited by tailoring training to industrial and regulatory needs. For example, investment by German development cooperation in a well-equipped industrial pharmacy training unit at St Luke's School of Pharmacy in Moshi has supported the training of regulatory staff from the region. However, industrial firms have argued for better adaptation of programmes to the staffing constraints they face. There is also a need for equipment maintenance training. External investors in training can work with local health and industrial interests to ensure their initiatives are designed to play a full role in skills development, including curriculum improvement and training that addresses the health-industrial interface.

Other training needs where external actors can bridge health and industrial needs include formulation and development (F&D) skills in local firms to extend product range, which requires hands-on work with industrially experienced teachers. One interviewee commented that there are Indian companies who would help, as collaborators to teach by example. External support for formal partnerships of this type would be very valuable and help local industry to innovate and adapt for local needs.

## ENGAGING WITH NATIONAL POLICIES TO COMBINE INDUSTRIAL PROTECTION WITH COMPETITION AND LOW PRICES

Governments in East Africa, certainly in Tanzania, Kenya, Uganda and Ethiopia, are looking at the 'Ghana model' of consistent and sustained government support and protection for the local pharmaceutical industry (see above). Key criticisms of industrial protection focus on the impact on prices and hence access, and external bodies are playing an important role in observing and documenting price differences (Ewen et al 2017). The challenge to external funders and other external actors, such as NGOs and the WHO, is to move away from principled opposition to all forms of industrial protection for pharmaceuticals, characterising tariffs as a tax on illness (Olcay and Laing 2005), towards a more nuanced and evidence-based position accepting the need for well-designed and time-limited protection (West and Banda 2016). The policy challenge is to ensure that, in the context of some 'infant industry' protection to allow firms to grow, domestic market competition is maintained and enhanced. External actors can contribute experience of effective competition legislation, undertake collaborative research that investigates price trends and their determinants, and support regional integration to enlarge local firms' scope for operation at scale. These are examples of constructive and critical engagement with a local policy agenda looking towards medium-term development of both industry and health.

## CONVENING AND PROBLEM-SOLVING: WORKING TOWARDS COHERENCE

One of the most appreciated roles of external agencies such as Germany's implementing organisations GIZ and PTB, in the interviews with industrialists, can be described as their convening power. GIZ support has been important in establishing the Federation of East African Pharmaceutical Manufacturers (FEAPM), the regional manufacturers' association, and in supporting manufacturers in improving their access to political levels. There is a perception that advocacy and working across ministries over perhaps 10 years, across the region, has led to more effective cross-sectoral public-private and health-industry consultation and policy debate, underlining the importance of sustaining good intersectoral working relationships as policies develop.

One experienced interviewee commented that a few key policy documents are essential to get industry-health collaboration started. However, he added, it is possible to waste a lot of time trying to ensure high-level coherence between policy documents in the early stages. Several interviewees pushed instead for an early focus on implementation, in the form of action plans, implementation processes, getting particular projects to work, and developing and using key legislative instruments. Where regional agreements lag, bilateral agreements between countries on particular issues – such as one East African country buying ARVs from another – can move the regional integration agenda forward step by step.

At national level, a Ministry of Health interviewee made the same point sharply: the aim was to promote more high-quality local production, one project at a time, solving issues and problems for each project through collaborative activity across ministries. The issue might be land for a new investor, or shifting local procurement practices within the existing legislative framework. It might be finding a way for a country, within the EAC zero external tariff, to institute some other forms of industrial protection for nascent industries. The industrial economist John Sutton has described<sup>38</sup> similarly the approach of the Ethiopian investment authority, working in detail on solving practical problems and constraints, investment by investment.

These arguments and approaches resonate with a strand in the current international policy literature (Srinivas 2016) that argues for a ‘problem-solving’ approach to development planning – an approach that builds up government capability by addressing specific problems in detail, in a collaborative way, rather than too much focus on policy documents. The Ministry of Health official quoted above said of this, their current way of working, ‘we used to think very narrowly’, but not anymore.

The proposition from these reflections is that external support can operate in assisting specific projects and issues, yet still achieve broader goals. There were some criticisms in the interviews of external actors who focused rather too much on running workshops. Interviewees’ appreciation was much greater for specific, agreed and targeted support for particular locally identified initiatives and linkage-building. A continuing policy debate, shaped by a few key policy documents and legislative instruments, can then galvanise more key stakeholders to join in, strengthening the benefits and improving policy coherence over time. Policy coherence is important, but it may be best thought of as an outcome of shared working on specific tasks, rather than a precondition or input to health-industry joint working.

<sup>38</sup> John Sutton, keynote talk at the REPOA Annual Research Workshop, Dar es Salaam, 2017.



# Conclusion: industrial development as a social determinant of health

There are many ways in which industrial development influences health, from employment and working conditions to levels of income and tax generated, as well as linkages with other allied sectors. This Evidence Brief has concentrated on a narrower set of effects: it has used stakeholder interviews and reviews of scholarly and practice literature to analyse the ways in which developmental synergies can be extracted from local pharmaceutical industrial development, associated technological and skills upgrading, and procurement of good quality local products for local access and use in health care.

This process of building health-industry synergy can be kick-started by top-level national or regional political leadership, as has been occurring in Tanzania, Kenya, Uganda and the EAC. A virtuous circle of support for industrial investment linked to improved local procurement procedures and funding and increased access by low-income patients can be achieved, but it requires substantial policy, infrastructure and funding commitment. The last section has suggested that a national project-based and problem-solving policy approach, with external support, can greatly contribute to success: it can create visible associations between improved business profits, expanding employment and strengthened health care, generating new patterns of collaboration and improved policy coherence.

To support these processes, development agencies and funders may need to enlarge their vision of the boundaries of their role and the tenor of their strategic focus, and at the same time shift patterns of involvement further. International health agencies, even when working on both sides of the health-industry 'fence' do not easily link up these spatial and temporal activities. An example is The Global Fund, whose active though limited contribution to health system strengthening appears at present to be delinked from its efforts to promote local procurement. Similarly, the WHO's role in supporting technical upgrading by manufacturers, while linked to achieving WHO-prequalification, is not linked into its health system strengthening work in any clearly articulated way.

As discussed above, public health has enlarged its vision recently to include many intersectoral social determinants of population health. However, the impact of industrial development on health is still generally overlooked. Building more robust African health systems requires – and will effectively employ – the scientific and technological capabilities and skills generated by industrial development in pharmaceuticals and medical supplies. As African governments develop their commitment to industrialisation, the global health community has a lot to contribute in supporting local health systems to extract the maximum benefits for public health.

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# References

- ACT Watch Group et al. (2017a). The malaria testing and treatment market in Kinshasa, Democratic Republic of the Congo, 2013. *Malar J.* **16**, 94.
- ACT Watch Group et al. (2017b). What happened to anti-malarial markets after the Affordable Medicines Facility malaria pilot? Trends in ACT availability, price and market share from five African countries under continuation of the private sector co-payment mechanism. *Malar J.* **16**, 173.
- African Union (2007). *Pharmaceutical plan for Africa*. Addis Ababa: African Union Commission. Available at: [www.unido.org/fileadmin/user\\_media/Services/PSD/BEP/Pharmaceutical%20manufacturing%20plan%20for%20Africa-English.pdf](http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Pharmaceutical%20manufacturing%20plan%20for%20Africa-English.pdf)
- African Union (2012). *Pharmaceutical manufacturing plan for Africa business plan*. Addis Ababa: African Union Commission. Available at: <http://sa.au.int/en/sites/default/files/pmpa%20bp%20ebook.pdf>
- Ahmed SM et al. (2013). Harnessing pluralism for better health in Bangladesh. *The Lancet.* **382**(9906), 1746-1755.
- Aldis W (2008). *Health security as a public health concept: a critical analysis*. Health Policy and Planning. **23**(6), 369-375.
- AVMI/UNIDO/WHO (forthcoming). *VMPA study: Vaccine manufacturing and procurement in Africa*.
- Banda G, Wangwe S and Mackintosh M (2016a). Making medicines in Africa: an historical political economy overview. In Mackintosh M et al. (eds.). *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.
- Banda G et al. (2016b). *Pharmaceutical standards: the road to improvement and their role in technological capability upgrading in Africa*. In Mackintosh M et al. (eds.). *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.
- Battams S and Matlin S (2013). Discussing a definition of global health. *Global health diplomacy briefing*. Geneva: Global Health Programme, The Graduate Institute. Available at: [http://graduateinstitute.ch/files/live/sites/iheid/files/sites/globalhealth/shared/1894/Publications/Publications%202013/Definition\\_Global\\_Health\\_v3.pdf](http://graduateinstitute.ch/files/live/sites/iheid/files/sites/globalhealth/shared/1894/Publications/Publications%202013/Definition_Global_Health_v3.pdf)
- Berger M et al. (2010). *Strengthening pharmaceutical innovation in Africa*. Geneva and Johannesburg: Council on Health Research for Development (COHRED) and The New Partnership for Africa's Development (NEPAD) Agency of the African Union. Available at: [www.nepad.org/download/file/fid/600%20](http://www.nepad.org/download/file/fid/600%20)
- Bigdeli M, Peters DH and Wagner AK (2014). *Medicines in health systems: advancing access, affordability and appropriate use*. Geneva: Alliance for Health Policy and Systems Research, World Health Organization.
- BMI (2016a). *Tanzania pharmaceuticals and healthcare market report Q3*. London: BMI Research, Business Monitor International Ltd.
- BMI (2016b). *Ghana pharmaceutical and healthcare report Q1 2016*. London: BMI Research, Business Monitor International Ltd.
- BMI (2017). *Tanzania pharmaceuticals and healthcare market report Q4*. London: BMI Research, Business Monitor International Ltd.

Chaudhuri S, Mackintosh M and Mujinja PGM (2010). Indian generics producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania. *European Journal of Development Research*. **22**(4), 451-468.

Chaudhuri S and West A (2014). Can local producers compete with low cost imports? A simulation study of pharmaceutical industry in low income Africa. *Innovation and Development*. **5**(1), 23-38.

Chowdhury MR et al. (2013). The Bangladesh paradox: exceptional health achievement despite economic poverty. *The Lancet*. **382**(9906), 1734-1745.

Church K et al. (2017). Identifying gaps in HIV service delivery across the diagnosis-to-treatment cascade: findings from health facility surveys in six sub-Saharan countries. *Journal of the International AIDS Society*. **20**, 21188.

Cohen JM et al. (2010). A pharmacy too far? Equity and spatial distribution of outcomes in the delivery of subsidized artemisinin-based combination therapies through private drug shops. *BMC Health Services Research*. **10**(Suppl 1): S6.

Commission on Social Determinants of Health (CSDH) (2008). *Closing the gap in a generation: health equity through action on the social determinants of health*. Final Report of the Commission on Social Determinants of Health. Geneva: World Health Organization. [http://apps.who.int/iris/bitstream/10665/43943/1/9789241563703\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/43943/1/9789241563703_eng.pdf)

East African Community (EAC) (2011). *Regional pharmaceutical manufacturing plan of action 2012-2016*. Arusha: EAC Secretariat. Available at: [http://feapm.com/fileadmin/user\\_upload/documents/EAC\\_Regional\\_Pharmaceutical\\_Manufacturing\\_Plan\\_of\\_Action.pdf](http://feapm.com/fileadmin/user_upload/documents/EAC_Regional_Pharmaceutical_Manufacturing_Plan_of_Action.pdf)

Elbe S (2010). *Security and Global Health*. Cambridge: Polity Press.

Elbe, S. (2011) 'Pandemics on the Radar Screen: Health Security, Infectious Disease and the Medicalisation of Insecurity', *Political Studies*, **59** (4), 848-66.

Ewen M et al (2017) Prices and availability of locally produced and imported medicines in Ethiopia and Tanzania. *Journal of Pharmaceutical Policy and Practice*. **10**, 7.

Federal Democratic Republic of Ethiopia (FDRE) (2015). *National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015-2025): Developing the pharmaceutical industry and improving access*. Addis Ababa: Ministry of Health and Ministry of Industry.

Flahault A et al. (2016). From global health security to global health solidarity and sustainability. *Bulletin of the World Health Organization*. **94**, 863.

Fortunak J et al. (2016). Raising the technological level: the scope for API, excipients, and biologicals manufacture in Africa. In Mackintosh M et al. (eds.). *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.

GBD 2015 HIV Collaborators (2016). Estimates of global, regional, and national incidence, prevalence, and mortality of HIV, 1980-2015: the Global Burden of Disease Study 2015. *Lancet HIV*. **3**(8), e361-87.

Gebre-Mariam T, Tahir K and Gebre-Amanuel S (2016). Bringing industrial and health policies closer: reviving pharmaceutical production in Ethiopia. In Mackintosh M et al. (eds.). *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.

Government of Kenya (2010). *National industrialisation policy framework*, Draft Five. Nairobi: Ministry of Industrialisation. Available at: <http://www.trademarksa.org/sites/default/files/publications/EAC%20Kenya%20National%20Industrialization%20Policy%20Framework%20-%20Combined%2018-11-2010%20Revised.pdf>

Government of Uganda (2002). *Uganda national drug policy*. Kampala: Ministry of Health.

Institute for Health Metrics and Evaluation (IHME) (2017). *Financing global health 2016: Development assistance, public and private health spending for the pursuit of universal health coverage*. Seattle: IHME, University of Washington. Available at: [http://www.healthdata.org/sites/default/files/files/policy\\_report/FGH/2017/IHME\\_FGH2016\\_Technical-Report.pdf](http://www.healthdata.org/sites/default/files/files/policy_report/FGH/2017/IHME_FGH2016_Technical-Report.pdf)

- Kaplan W and Laing R (2005). *Local production of pharmaceuticals: industrial policy and access to medicines. An overview of key concepts, issues and opportunities for future research*. Health, Nutrition and Population Discussion Paper. Washington, DC: World Bank.
- Kaplan WA, Ritz LS and Vitello M (2011). Local production of medical technologies and its effect on access in low and middle income countries: a systematic review of the literature. *Southern Med Review*. **4**(2), 51-61.
- Kardas-Nelson M (2015). Can (and should) Africa make its own medicines? *BMJ*. 350:h2178.
- Kariuki J et al. (2015) *Local supply chains for medicines and medical supplies in Kenya: understanding the challenges*. Inclusive Bioeconomy Programme Issue Paper 1. Nairobi: African Centre for Technology Studies. Available at: <http://iphsp.acts-net.org/images/WorkingBriefs/Issue-Paper-0012015.pdf>
- Kenya National Bureau of Statistics (KNBS) (2014). *Kenya economic survey 2014*. Nairobi: KNBS.
- Kenya National Bureau of Statistics (KNBS) (2015). *Statistical abstract 2015*. Nairobi: KNBS.
- Kickbusch I (2006). The need for a European strategy on global health. *Scand J Public Health*. **34**(6), 561-5.
- Koplan JP et al. (2009). Towards a common definition of global health. *The Lancet*. **373**(9679), 1993-5.
- López-Casasnovas G, Rivera B and Currais L (eds.) (2005). *Health and economic growth: Findings and policy implications*. Cambridge, Mass.: MIT Press.
- Macfarlane S, Jacobs M and Kaaya E (2008). In the name of global health: trends in academic institutions. *J Public Health Policy*. **29**(4): 383-401.
- Mackintosh M et al. (eds.) (2016a) *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan. Open access. Available at: [www.palgrave.com/us/book/9781137546463](http://www.palgrave.com/us/book/9781137546463)
- Mackintosh M et al. (2016b). What is the private sector? Understanding private provision in the health systems of low-income and middle-income countries. *The Lancet*. **388**(10044), 596–605. Available at: [www.thelancet.com/series/private-sector-health](http://www.thelancet.com/series/private-sector-health)
- Mackintosh M, Chataway J and Wuyts M (2007). Promoting innovation, productivity and industrial growth and reducing poverty: bridging the policy gap. *European Journal of Development Research*. **19**(1), 1-11.
- Mackintosh M and Mujinja PGM (2010). Markets and policy challenges in access to essential medicines for endemic disease. *Journal of African Economies*. **19**(Supp 3), iii166–iii200.
- Mackintosh M and Tibandebage P (2016). *Health as a productive sector: integrating health and industrial policy*. ESRF Background Paper No 8 for the Tanzania Human Development Report 2017. Dar es Salaam: Economic and Social Research Foundation. Available at: <http://esrf.or.tz/docs/THDR2017BP-8.pdf>
- McKinsey & Company (2015). *Insights into pharmaceuticals and medical products Africa: A continent of opportunity for pharma and patients*. <http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/africa-a-continent-of-opportunity-for-pharma-and-patients>
- Médicins sans Frontières (MSF) (2016). *Untangling the web of anti-retroviral price reductions 18th Edition-July 2016*. Geneva: MSF. Available at: [www.msfacecess.org/sites/default/files/HIV\\_report\\_Untangling-the-web-18thed\\_ENG\\_2016.pdf](http://www.msfacecess.org/sites/default/files/HIV_report_Untangling-the-web-18thed_ENG_2016.pdf)
- Ministry of Health (2016). Consultation on Policy Coherence on Improving Health Technology Access and Delivery. March. Dar es Salaam: Ministry of Health.
- Ministry of Industry (MIT) and UNIDO (2012). *Tanzania competitiveness report*. Dar es Salaam: MIT and President's Office Planning Commission of the United Republic of Tanzania and UNIDO.
- Ministry of Medical Services and Ministry of Public Health and Sanitation (MoMS & MPHS) (2010). *Sessional paper on national pharmaceutical policy*. Nairobi: MoMS and MPHS. Available at: <http://apps.who.int/medicinedocs/en/d/Js18697en/>



- Mohamed N (2009). The role of local manufacturers in improving access to essential medicines: creating opportunities for the scale up of local pharmaceutical production. *Africa Health*. 32(1), 40-42.
- Morris A et al. (2015). Price subsidies increase the use of private sector ACTs: evidence from a systematic review. *Health Policy and Planning*. 30(3), 397-405.
- Mugwagwa J (2015). *Innovating for public health: towards harmonized medicines regulatory systems in Sub-Saharan Africa*. International Journal of Technology Management and Sustainable Development. 14(3), 163-177.
- Mujinja PGM et al. (2014). Local production of pharmaceuticals in Africa and access to essential medicines: 'urban bias' in access to imported medicines in Tanzania and its policy implications. *Globalization and Health*. 10(12).
- Ogendi PO (2013). Access to essential medicines and the utilisation of compulsory licensing and parallel importation in Kenya and South Africa. LLM Thesis, University of Nairobi.
- Olcay M and Laing R (2005). Pharmaceutical tariffs: What is their effect on prices, protection of local industry and revenue generation? [www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf](http://www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf)
- Onwujekwe O et al. (2011). Constraints to universal coverage: inequities in health service use and expenditures for different health conditions and providers. *Int J Equity Health*. 10, 50.
- Reich M (1990). Why the Japanese don't export more pharmaceuticals: health policy as industrial policy. *California Management Review*. 32(2), 124-150.
- Republic of Ghana (2004). *Ghana National Drug Policy (Second Edition)*. Accra: Ministry of Health.
- Rokvic V and Jeftic Z (2015). Health issues as security issues. *Vojno Delo* 6, 53-69. [http://www.odbrana.mod.gov.rs/odbrana-stari/vojni\\_casopisi/arhiva/VD\\_6-2015/67-2015-6-06-Rokvic.pdf](http://www.odbrana.mod.gov.rs/odbrana-stari/vojni_casopisi/arhiva/VD_6-2015/67-2015-6-06-Rokvic.pdf)
- Rovira J (2006). Creating and promoting domestic drug manufacturing capacities: A solution for developing countries? In Roffe P, Tansey G and Vivas-Eugui D (eds.). *Negotiating health. Intellectual property and access to medicines*. London: Earthscan Publications Ltd.
- Rushton S (2011). Global health security: Security for whom? Security from what? *Political Studies*. 59, 779-796.
- Russo G and de Oliveira L (2016). South-South collaboration in pharmaceuticals: manufacturing anti-retroviral medicines in Mozambique. In Mackintosh M et al. (eds.) *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.
- Seiter A (2005). *Pharmaceuticals: Local manufacturing*. HNP Brief 3. Washington, DC: World Bank. <http://apps.who.int/medicinedocs/documents/s16758e/s16758e.pdf>
- Sidibé M, Yong L and Chan M (2014). Commodities for better health in Africa: time to invest locally. *Bulletin of the World Health Organization*. 92, 387-387A.
- Simonetti R, Clark N and Wamae W (2016). Pharmaceuticals in Kenya: the evolution of technological capabilities. In Mackintosh M et al. (eds.) *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.
- Srinivas S (2012). *Market menagerie. Health and development in late industrial states*. Stanford, California: Stanford University Press.
- Srinivas S (2016). Healthy industries and unhealthy populations: lessons from Indian problem-solving. In Mackintosh M et al. (eds.) *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.
- Statistica (2017). *Pharmaceutical market: worldwide revenue 2001-2015*
- Sudoi RK et al. (2012). The magnitude and trend of artemether-lumefantrine stock-outs at public health facilities in Kenya. *Malar J*. 11, 37.

Sutton J (2012). *Competing in capabilities: The globalization process*. Oxford: Oxford University Press.

Tait J and Banda G (2016). *Proportionate and adaptive governance of innovative technologies: The role of regulations, guidelines and standards*. London: British Standards Institution. [www.bsigroup.com/LocalFiles/en-GB/PAS/Homepage/Summary%20Report%20-%20Executive%20summary%20-%20final.pdf](http://www.bsigroup.com/LocalFiles/en-GB/PAS/Homepage/Summary%20Report%20-%20Executive%20summary%20-%20final.pdf)

Talisuna AO et al. (2012). Closing the access barrier for effective anti-malarials in the private sector in rural Uganda: consortium for ACT private sector subsidy (CAPSS) pilot study. *Malar J*. 11, 356.

The Global Fund (2017). *37th Board Meeting: Executive Summary: Global Fund Financial Performance and Financial Statements GF/B37/29*. 03-04 May 2017, Kigali, Rwanda. Geneva: The Global Fund. [www.theglobalfund.org/en/board/meetings/37/](http://www.theglobalfund.org/en/board/meetings/37/)

Thomas G (1994). Implicit industrial policy: the triumph of Britain and the failure of France in global pharmaceuticals. *Industrial and Corporate Change*. 3(2), 451-489.

Tibandebage P et al. (2014). *The Tanzanian health sector as buyer and user of medicines and other essential supplies*. Working Paper 14/5 Dar es Salaam: REPOA. [www.repoa.or.tz/documents/REPOA\\_WP\\_14\\_5.pdf](http://www.repoa.or.tz/documents/REPOA_WP_14_5.pdf)

Tibandebage P et al. (2016) Pharmaceutical manufacturing decline in Tanzania: how possible is a turnaround to growth? In Mackintosh M et al. (eds.). *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.

United Nations (UN) (2015). *Taking stock of the global partnership for development. Millennium Development Goal 8. MDG Gap Task Force Report*. New York: United Nations. [www.un.org/en/development/desa/policy/mdg\\_gap/mdg\\_gap2015/2015GAP\\_FULLREPORT\\_EN.pdf](http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2015/2015GAP_FULLREPORT_EN.pdf)

United Nations Conference on Trade and Development (UNCTAD) (2011). *Local production of pharmaceuticals and related technology transfer in developing countries: a series of case studies*. Geneva: UNCTAD.

United Nations Industrial Development Organisation (UNIDO) (2010a). *Pharmaceutical profile: Kenya*. Vienna: UNIDO. [www.unido.org/fileadmin/user\\_media/Services/PSD/BEP/Kenya\\_Pharma%20Sector%20profile\\_TEGLO05015\\_Ebook.pdf](http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Kenya_Pharma%20Sector%20profile_TEGLO05015_Ebook.pdf)

United Nations Industrial Development Organisation (UNIDO) (2010b). *Pharmaceutical Profile: Uganda*. Vienna: UNIDO. [www.unido.org/fileadmin/user\\_media/Services/PSD/BEP/Uganda%20Pharma%20Sector%20Profile\\_TEGLO05015\\_Ebook\\_.pdf](http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Uganda%20Pharma%20Sector%20Profile_TEGLO05015_Ebook_.pdf)

United Republic of Tanzania (URT) (2012). *Annual survey of industrial production 2009: Statistical report*. Dar es Salaam Ministry of Trade and Industry.

United Republic of Tanzania (URT) (2013). *Census of industrial production 2013. Tanzania Mainland*. Dar es Salaam: National Bureau of Statistics.

United Republic of Tanzania (URT) (2014) *Household Budget Survey Main Report 2011/12*. Dar es Salaam: National Bureau of Statistics

United Republic of Tanzania (URT) (2015). *Health sector strategic plan, July 2015-June 2020*. Dar es Salaam: Ministry of Health. [www.tzdpd.or.tz/fileadmin/documents/dpg\\_internal/dpg\\_working\\_groups\\_clusters/cluster\\_2/health/Key\\_Sector\\_Documents/Induction\\_Pack/Final\\_HSSP\\_IV\\_Vs1.0\\_260815.pdf](http://www.tzdpd.or.tz/fileadmin/documents/dpg_internal/dpg_working_groups_clusters/cluster_2/health/Key_Sector_Documents/Induction_Pack/Final_HSSP_IV_Vs1.0_260815.pdf)

United Republic of Tanzania (URT) (2016). *National five year development plan, 2016/2017-2020/2021*. Dar es Salaam: Ministry of Finance and Planning. [www.mof.go.tz/mofdocs/msemaji/Five%202016\\_17\\_2020\\_21.pdf](http://www.mof.go.tz/mofdocs/msemaji/Five%202016_17_2020_21.pdf)

Waako PJ et al. (2009). Existing capacity to manage pharmaceuticals and related commodities in East Africa. *Human Resources for Health*. 7, 21.

Wagner AK et al. (2011). Access to care and medicines, burden of health care expenditures, and risk protection: results from the World Health Survey. *Health Policy*. 100(2-3), 151-58.

- Waning B, Diedrichsen E and Moon S (2010). A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. *J Int AIDS Soc.* 13, 35.
- West A and Banda G (2016). Finance and incentives to support the development of national pharmaceutical industries. In Mackintosh M et al. (eds.). *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan.
- Wiedenmayer KA et al. (2015). *The reality of task shifting in medicines management – a case study from Tanzania*. Journal of Pharmaceutical Policy and Practice. 8(1), 13.
- Wilson KR, Kohler JC and Ovtcharenko N (2012). The make or buy debate: considering the limitations of domestic production in Tanzania. *Global Health.* 8, 20.
- Wirtz VJ et al. (2017). Essential medicines for universal health coverage. *The Lancet.* 389(10067), 403-476
- World Bank (2016). *UHC in Africa: an agenda for action*. Washington DC: World Bank. <http://documents.worldbank.org/curated/en/735071472096342073/pdf/108008-v1-REVISED-PUBLIC-Main-report-TICAD-UHC-Framework-FINAL.pdf>
- World Health Organization (WHO) (2011a). *Local production for access to medical products: Developing a framework to improve public health*. Geneva: WHO.
- World Health Organization (WHO) (2011b). *The world medicines situation*. Geneva: WHO. [http://www.who.int/medicines/areas/policy/world\\_medicines\\_situation/en/](http://www.who.int/medicines/areas/policy/world_medicines_situation/en/)
- World Health Organization (WHO) (2011c). Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa. Geneva: WHO. [https://extranet.who.int/prequal/sites/default/files/documents/WHO\\_QAMSA\\_report\\_1.pdf](https://extranet.who.int/prequal/sites/default/files/documents/WHO_QAMSA_report_1.pdf)
- World Health Organization (WHO) (2013). *World health statistics*. Geneva: WHO.
- World Health Organization (WHO) (2015). *Report on the status of major health risk factors for noncommunicable diseases*. Brazzaville: WHO Regional Office for Africa.
- World Health Organization (WHO) (2016) *Atlas of African health statistics 2016. Health situation analysis of the African Region*. WHO Regional Office for Africa, Brazzaville, Congo
- World Health Organization (WHO) (2017a). *Towards access 2030: WHO medicines and health products programme strategic framework 2016 – 2030*. Geneva: WHO. [www.who.int/medicines/publications/Towards\\_Access\\_2030\\_Final.pdf?ua=1](http://www.who.int/medicines/publications/Towards_Access_2030_Final.pdf?ua=1)
- World Health Organization (WHO) (2017b). *World Health Statistics*. Geneva: WHO.
- World Health Organization (WHO) (2017c) *Joint External Evaluation of IHR Core Capacities, United Republic of Tanzania, Mission Report February 2016*. Geneva, WHO
- World Health Organization/World Bank (2017). *Healthy systems for universal health coverage – A joint vision for healthy lives*. Geneva and Washington, DC: WHO and International Bank for Reconstruction and Development/World Bank. [https://www.uhc2030.org/fileadmin/uploads/ihp/Documents/About\\_IHP\\_/mgt\\_arrangements\\_\\_\\_docs/UHC2030\\_Official\\_documents/UHC2030\\_vision\\_paper\\_WEB2.pdf](https://www.uhc2030.org/fileadmin/uploads/ihp/Documents/About_IHP_/mgt_arrangements___docs/UHC2030_Official_documents/UHC2030_vision_paper_WEB2.pdf)
- Yadav P (2015). Health product supply chains in developing countries: diagnosis of the root causes of underperformance and an agenda for reform. *Health Systems and Reform.* 1(2), 142-154.

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**AUTHORS**

Maureen Mackintosh, Julius Mugwagwa, Geoffrey Banda,  
Jires Tunguhole

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Karsten van der Oord

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**ADDRESSES OF THE BMZ OFFICES**

→ BMZ Bonn

Dahlmannstraße 4  
53113 Bonn

Tel. +49 (0) 228 99 535 - 0

Fax +49 (0) 228 99 535 - 3500

→ BMZ Berlin im Europahaus

Stresemannstraße 94  
10963 Berlin

Tel. +49 (0) 30 18 535 - 0

Fax +49 (0) 30 18 535 - 2501

**CONTACT**

poststelle@bmz.bund.de  
www.bmz.de

